

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL PRESCRIPTION) No. 17-md-2804
5 OPIATE LITIGATION) MDL NO. 2804
6)
7 APPLIES TO ALL CASES) Hon. Dan A. Polster
8)

9 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
10 CONFIDENTIALITY REVIEW

11 VIDEO DEPOSITION OF KEVIN VORDERSTRASSE

12 December 5, 2018

13 9:12 a.m.

14 Reporter: John Arndt, CSR, CCR, RDR, CRR
15 CSR No. 084-004605
16 CCR No. 1186

1 DEPOSITION OF KEVIN VORDERSTRASSE
produced, sworn, and examined on December 5, 2018, at
2 Stinson Leonard Street LLP, 7700 Forsyth Boulevard,
Suite 1100, in the City of St. Louis, State of
3 Missouri, before John Arndt, a Certified Shorthand
Reporter and Certified Court Reporter.

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18

(Exhibits are attached.)

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1 THE VIDEOGRAPHER: We are now on the
2 record. My name is James Arndt. I'm a videographer
3 for Golkow Litigation Services. Today's date is
4 December 5th, 2018, and the time is 9:12 AM. This
5 video deposition is being held in St. Louis, Missouri,
6 in the matter of the National Prescription Opiate
7 Litigation for the United States District Court for the
8 Northern District of Ohio, Eastern Division. The
9 deponent is Kevin Vorderstrasse. Will counsel please
10 identify themselves?

11 MR. KO: Good morning, everyone. David Ko
12 of Keller Rohrbach on behalf of the plaintiffs.

13 MS. KEECH: Erika Keech from Keller
14 Rohrbach on behalf of the plaintiffs.

15 MS. HERZFELD: Tricia Herzfeld on behalf
16 of the Tennessee plaintiffs.

17 MR. HOLLINGSWORTH: Adam Hollingsworth on
18 behalf of Walmart.

19 MR. BUSHUR: Joseph Bushur on behalf of
20 Cardinal Health.

21 MR. GOLDSTEIN: Joshua Goldstein on behalf
22 of Mallinckrodt LLC and SpecGX LLC.

23 MR. TSAI: Good morning. Rocky Tsai,
24 Ropes & Gray, on behalf of the witness and Mallinckrodt

1 LLC.

2 [Discussion off the record.]

3 THE VIDEOGRAPHER: Will counsel on the
4 phone please identify themselves?

5 MR. YINGLING: This is Patrick Yingling
6 for AmerisourceBergen.

7 MS. SUNDERLAND: This is Sara
8 Sunderland --

9 MS. ZOLLER: Rebecca Zoller --

10 MS. SUNDERLAND: This is Sara
11 Sunderland for McKesson.

12 MS. ZOLLER: Rebecca Zoller with Arnold &
13 Porter on behalf of the Endo and Par defendants.

14 MS. BURKE: Maura Burke with Fox
15 Rothschild on behalf of Validus Pharmaceuticals.

16 THE VIDEOGRAPHER: The court reporter is
17 John Arndt and he will now swear in the witness.

18

19 The witness, KEVIN VORDERSTRASSE, first having
20 been duly sworn, testified as follows:

21 QUESTIONS BY MR. KO:

22 [9:14 a.m.]

23 Q. Good morning.

24 A. Good morning.

1 Q. Could you please state and spell your name
2 for the record?

3 A. My name is Kevin Vorderstrasse.
4 V-O-R-D-E-R-S-T-R-A-S-S-E.

5 Q. And Mr. Vorderstrasse, where do you
6 currently reside?

7 A. I currently reside in St. Peters,
8 Missouri.

9 Q. And Mr. Vorderstrasse, have you had your
10 deposition taken before?

11 A. No, I have not.

12 Q. It's your first time? Congratulations.

13 A. Thank you.

14 Q. Let me go over some ground rules that are
15 important. These court reporters here have the most
16 important job here, so it's very important that we try
17 and create a clean record to the extent that we can, so
18 I would please ask that you wait until I finish my
19 question before you respond, and I will likewise wait
20 until you finish your response before I move onto my
21 next question. In other words, let's not talk over
22 each other. Okay?

23 A. Good.

24 Q. And to the extent I ask a yes-or-no

1 question and your answer is indeed yes or no, I would
2 ask that you make that clear and audible, rather than
3 simply shaking your head or otherwise revealing a
4 response that's inaudible. Okay?

5 A. Okay.

6 Q. And from time to time, your counsel, Mr.
7 Tsai, might object to my questions, but I'd ask that
8 you please answer them unless he clearly instructs you
9 otherwise. Okay?

10 A. Okay.

11 Q. And throughout the day we'll be taking
12 some breaks. It will be a long one. Hopefully it
13 won't be too long, but whenever you feel like you need
14 a break, please let me know and we'll try to do our
15 best to accommodate.

16 A. Good.

17 Q. And do you mind if I call you Kevin?

18 A. No, that's perfectly fine.

19 Q. Okay. And Kevin, you were just sworn in,
20 but is there anything that you can think of today or
21 this morning that will prevent you from testifying
22 truthfully or honestly today?

23 A. No.

24 Q. Thank you. I'm going to hand you a copy

1 of what we're going to call KV Exhibit 1.

2 [Exhibit Mallinckrodt-Vorderstrasse-001
3 marked for identification.]

4 Q. Kevin, do you recognize that document?

5 A. Yes, I believe so.

6 Q. And what is it, to your understanding?

7 A. This is the notice of deposition from
8 Mallinckrodt for the 30(b)6 deposition with a listing
9 of topics.

10 Q. And you understand that there are topics
11 that plaintiffs in this case have asked Mallinckrodt to
12 respond to and that you have been designated to testify
13 on some of these topics? Is that your understanding?

14 A. Yes.

15 Q. And before we get into the actual topics,
16 as noted in this deposition, Mallinckrodt is defined as
17 Mallinckrodt PLC, Mallinckrodt LLC, and SpecGX LLC, and
18 I know that there is an ongoing dispute with respect to
19 the PLC that I'll note for the record and plaintiffs
20 reserve all rights with respect to the PLC, but for
21 today I understand that you're testifying on behalf of
22 the LLC and SpecGX LLC. Is that correct?

23 A. That's correct.

24 Q. And today we'll also be looking at some

1 documents that reflect some Covidien e-mail addresses
2 and some plan documents and marketing material that
3 reflect Covidien materials. Is it fair -- or can we
4 agree for purposes of today that Mallinckrodt -- or
5 excuse me -- that Covidien refers to Mallinckrodt LLC
6 and SpecGX as well?

7 A. Yes, that makes sense to me.

8 Q. By the way, other than the LLC --
9 Mallinckrodt LLC and SpecGX LLC and Covidien, are there
10 any other related entities that were involved with the
11 manufacturing and marketing and promotion of
12 prescription opioids that you are aware of?

13 A. Not that I'm aware of.

14 Q. And for the record, with respect to the
15 PLC, have you done -- have you had any communications
16 with any employees or individuals that work for the
17 PLC?

18 MR. TSAI: I'll object for the record. As
19 referenced, the governing court order makes clear that
20 claims with respect to foreign entities that did not
21 sell or distribute prescription opioids to the United
22 States is prohibited and in fact is the grounds for
23 sanctions.

24 That description applies precisely to PLC,

1 which is an Irish entity that never made, sold,
2 marketed, or distributed any prescription opioids to
3 the United States, much less to the Ohio jurisdictions
4 at issue. So with that noted, as referenced, there's
5 negotiations about potentially dismissing PLC, and I
6 would note our objection for the record.

7 Q. (By Mr. Ko) So your attorney had a long
8 objection. The question I would ask you to still
9 answer, unless he instructs you otherwise. Have you
10 had any communications with any employees or
11 individuals that work for the PLC?

12 A. I have in the past communicated with
13 individuals that work at the PLC, yes.

14 Q. And approximately how many individuals?

15 A. Approximately three to five.

16 Q. And have any of these communications
17 involved, as your counsel described, communications
18 with respect to the marketing and distribution of
19 prescription opioids in the United States?

20 A. Not that I can recollect.

21 Q. Now, turning back to this notice, as we
22 discussed before, you have been designated to speak on
23 behalf of the company on some topics, and it is my
24 understanding that you have been designated to speak on

1 behalf of Mallinckrodt for Topics 10, 11 -- let's try
2 this. My understanding is that you have been
3 designated to speak on behalf of Mallinckrodt for
4 Topics 10, 11, and 12. Is that correct?

5 A. That's correct.

6 Q. And also Topics 17 and 18?

7 A. That is correct.

8 Q. And also Topic 19?

9 A. Correct.

10 Q. Let's see. Topics 20, 21, and 22?

11 A. Correct.

12 Q. I believe you're also testifying on behalf
13 of Mallinckrodt for Topics 27 and 28. Is that correct?
14 And I know there's a carveout in 27. We'll get to that
15 in a second.

16 A. Yes, that's correct.

17 Q. And then Topics 29?

18 A. Yes.

19 Q. And I think lastly Topic 31.

20 A. Yes, that's correct.

21 Q. Are all those topics, with the exception of
22 the carveout in 27, topics that you will be testifying
23 on behalf of Mallinckrodt today?

24 A. Yes.

1 Q. Are there any other topics that I missed?

2 A. No.

3 Q. And then going back to Topic 27, it's my
4 understanding that you will be testifying as to that
5 topic with the exception of the phrase distribution and
6 diversion and suspicious order monitoring and
7 compliance. So in other words -- let me rephrase.

8 A. Uh-huh.

9 Q. For Topic 27, you will be testifying on
10 behalf of Mallinckrodt for the following topic. To the
11 extent not encompassed within other topics, your
12 marketing, promotion, sales, and pharmacovigilance
13 concerning your generic opioid products.

14 A. Yes, that is correct.

15 Q. Thank you. Now, just for the record, so
16 you are testifying on behalf of Mallinckrodt and you're
17 providing corporate testimony on behalf of these
18 entities. Do you understand that?

19 A. Yes, I do.

20 Q. And you're not testifying in your
21 individual capacity here today?

22 A. Yes.

23 Q. Can you describe to the court what you did
24 to prepare for this deposition?

1 A. In general I reviewed documents and had
2 conversations with employees through counsel in order
3 to refresh my memory or to learn topics with which I
4 was not originally familiar, as well as reviewing
5 documents that I was familiar with.

6 Q. And did you meet with counsel to prepare
7 for this deposition?

8 A. Yes.

9 Q. And which counsel did you meet with?

10 A. With counsel from Ropes & Gray. Several
11 different attorneys.

12 Q. Which attorneys?

13 A. Bill Davison, Rocky Tsai, Josh Goldstein,
14 Andrew -- last name escapes me. As well as others who
15 I can't recall their name at this point.

16 Q. Was it Andrew O'Connor?

17 A. Yes. Thank you.

18 Q. And approximately how many times did you
19 meet with them and for how long?

20 A. We met on four different occasions.
21 Probably about 30 hours total.

22 Q. Some good preparation, it sounds like.

23 A. I think so.

24 Q. Sorry. I spoke over you. I broke my own

1 rule. And as far as the conversations with employees
2 you had -- why don't I do this? Why don't I hand you
3 what will now be marked as KV Exhibit 2?

4 [Exhibit Mallinckrodt-Vorderstrasse-002
5 marked for identification.]

6 Q. Does this document look familiar to you?

7 A. Yes, it does.

8 Q. And this document was produced to
9 plaintiffs this morning in advance of the deposition,
10 and it appears based on what I can tell at the time
11 that it comprises of materials you reviewed, among
12 other things, and people you spoke to at Mallinckrodt
13 to prepare for this deposition. Is that correct?

14 A. That is correct.

15 Q. And in terms of the individuals at
16 Mallinckrodt that you spoke with to prepare for this
17 deposition, there are some names that are listed in
18 this exhibit; is that correct?

19 A. Yes.

20 Q. And --

21 MR. TSAI: If I could just note for the
22 record, this Exhibit 2 was provided yesterday as well
23 as a courtesy copy provided this morning.

24 MR. KO: Okay. Well, for the record, the

1 actual document was not sent to us until this morning.

2 Q. (By Mr. Ko) The people that are listed
3 here include Melissa Falcone, Kathy Schaefer, George
4 Kegler, Jeff Kilper, and I believe that's all. Are
5 those the individuals that you spoke with in
6 preparation for this deposition today?

7 A. So in preparation for the deposition I
8 spoke with Melissa Falcone on a conversation where Bill
9 Davison from Ropes & Gray was present, and I reviewed
10 documents provided by Kathy Schaefer, George Kegler,
11 and Jeff Kilper, which were provided to me by my
12 attorneys.

13 Q. So the only person you actually spoke
14 with -- well, let's take a step back. Is Ms. Falcone
15 an employee at Mallinckrodt?

16 A. Yes, she is.

17 Q. A current employee?

18 A. Yes.

19 Q. And other than Ms. Falcone, is there any
20 other current or former employee at Mallinckrodt that
21 you spoke with in preparation for this deposition?

22 A. No.

23 Q. And this KV Exhibit 2 also indicates or
24 reflects some materials that you reviewed, and as you

1 just alluded to, you looked at some documents. Does
2 this exhibit constitute the entirety of the documents
3 that you reviewed in preparation for this deposition?

4 MR. TSAI: Object to the form. Go ahead.

5 A. This document provides a summary of the
6 documents which I reviewed. It does not detail out
7 each individual document.

8 Q. (By Mr. Ko) Okay. Were there any
9 personal documents you reviewed that are not contained
10 in the summary that you looked at in connection or in
11 preparation for this deposition?

12 A. No.

13 Q. In any of your meetings with your
14 attorneys or in your conversations with Ms. Falcone,
15 did you bring or raise any documents that are not
16 listed in this summary?

17 A. No.

18 Q. In terms of the documents that were
19 selected and are contained in the summary, did you
20 select any of the documents yourself, or were they all
21 provided by counsel or selected by counsel?

22 A. All of the documents that I reviewed were
23 selected by counsel and provided by counsel.

24 Q. Other than people at -- other than

1 employees at Mallinckrodt, both current and former, or
2 your counsel, did you speak with anyone else in
3 connection with preparing for this deposition today?

4 A. No, I did not.

5 Q. What is your current position at
6 Mallinckrodt?

7 A. My current position is senior director of
8 product management and analytics.

9 Q. And what are your primary roles and
10 responsibilities in that -- in connection with that
11 position?

12 A. I oversee the product management,
13 commercial analytics, and marketing activities in
14 support of our specialty generic segment, which
15 consists of our generic drugs, our addiction treatment
16 drugs, as well as our active ingredients business.

17 Q. So isolating on your role as a product
18 manager, are the products you described insofar as
19 generic drugs, addiction treatment, and active
20 ingredients -- are those the products that you're
21 referring to that you manage?

22 A. Yes, that's correct.

23 Q. And then with respect to generic drugs,
24 are they all prescription opioids, or are there other

1 generic drugs that you are product manager for?

2 A. We do manage drugs that are not
3 prescription opioids, yes.

4 Q. And approximately how many relative to the
5 generic drugs? And by how many, I mean -- why don't
6 you give the court an approximate percentage? So about
7 how many of the products you manage are generic
8 prescription opioids relative to the other types of
9 generic drugs that you manage?

10 A. Right. So our generic drug portfolio
11 consists of roughly half generic opioids and half other
12 generic drugs.

13 Q. Okay. That's helpful. Thank you. And
14 then with respect to addiction treatment, are those all
15 products that are addiction treatment for opioid use
16 disorder?

17 A. Yes, they are.

18 Q. And do those include buprenorphine?

19 A. Yes.

20 Q. And methadone?

21 A. Yes.

22 Q. Does Mallinckrodt manufacture any Vivitrol
23 or naltrexone?

24 A. Mallinckrodt manufactures the naltrexone

1 active ingredient. We do not manufacture Vivitrol, and
2 we also manufacture generic naltrexone tablets.

3 Q. And can you give the court a general
4 approximation as well of within the addiction treatment
5 space what percentage of drugs you manage relative to
6 the others?

7 A. Addiction treatment, in terms of number of
8 products, is less than 10 percent of our portfolio.

9 Q. And within that 10 percent, how much is --
10 approximately how much is dedicated to bup versus
11 methadone versus naltrexone?

12 A. Methadone is on a product basis roughly a
13 third for each -- buprenorphine, methadone, and
14 naltrexone -- but in terms of overall volume sold,
15 methadone is the majority of the sales.

16 Q. And has that generally been the case over
17 time since Mallinckrodt has manufactured and
18 distributed addiction treatment for opioid use
19 disorder-type drugs?

20 A. That has generally been the case. We have
21 only sold buprenorphine for the last several years, but
22 sold methadone before that.

23 Q. And in terms of the overall -- in terms of
24 these drugs representing 10 percent of the overall

1 portfolio, has that grown -- has that increased or
2 decreased over time?

3 A. I would say it has decreased over time as
4 the rest of the portfolio has grown.

5 Q. And in connection with your role as a
6 product manager, how long have you been in that role?

7 A. I've been in my current role for a year
8 and eight months.

9 Q. And who do you primarily report to?

10 A. My current supervisor is Karen Lasker.

11 Q. And what's her position?

12 A. She is the vice-president of commercial
13 operations for specialty generics.

14 Q. And I won't ask all the people that report
15 to you, but generally speaking, what departments or
16 groups report to you?

17 A. Generally speaking, product management,
18 commercial analytics, and marketing.

19 Q. And approximately how many individuals do
20 you oversee and/or report to you?

21 A. Eight.

22 Q. I'm going to hand you a copy of what the
23 court reporter is going to mark as KV Exhibit 3.

24 [Exhibit Mallinckrodt-Vorderstrasse-003

1 marked for identification.]

2 Q. Kevin, does this document look familiar to
3 you?

4 A. Yes, it does.

5 Q. I'll note for the record that it is your
6 LinkedIn profile --

7 A. Uh-huh.

8 Q. -- as of a few days ago. Does it appear
9 to be the same as how you have posted this on your
10 LinkedIn website?

11 A. Yes, this appears to be accurate.

12 Q. And I won't go over in detail all these
13 things that you've done, but I do want to focus on a
14 few things that you list as your skills. Is it fair to
15 say -- so in your LinkedIn profile you have your
16 summary where you list kind of the highlights of what
17 you do at Mallinckrodt, and then below that you list a
18 series of phrases, for lack of a better term, that talk
19 about the types of skills that you have. Is that fair
20 to say?

21 A. Yes, that's fair.

22 Q. So in other words, commercial strategy is
23 something you have experience in?

24 A. Correct.

1 Q. And I want to focus on a few of these, in
2 particular return on investment marketing strategy,
3 which you can see up there on the screen. Can you
4 describe to the court what you mean by that?

5 A. So that -- the words you're referencing
6 are actually two separate items.

7 Q. Okay. That's helpful.

8 A. Return on investment is separate from
9 marketing strategy.

10 Q. Okay. Well, then I won't bore everyone
11 with marketing strategy because we have a general
12 understanding of that, but why don't you describe to
13 the court in your terms what return on investment
14 means?

15 A. In the context of my profile, return on
16 investment refers to my involvement in business
17 development and licensing projects and performing
18 financial analysis on the prospective acquisition of
19 products or companies.

20 Q. And can you describe to the court why that
21 skill is important at Mallinckrodt?

22 A. Mallinckrodt is a for-profit business, and
23 as such, when we look to make investments or acquire
24 assets, we want to make sure that we are investing an

1 appropriate amount in order to make that investment
2 worth it for the company.

3 Q. And have you performed -- can I call
4 return on investment ROI for purposes of the deposition
5 today?

6 A. Yes, that's fine.

7 Q. Have you performed ROI-type activities or
8 tasks at Mallinckrodt in connection with the
9 manufacture and sale and distribution of prescription
10 opioids?

11 MR. TSAI: Object to the form. Go ahead.

12 A. I have performed return-on-investment
13 analysis relative to approval of projects for
14 development of new products, including opioids.

15 Q. (By Mr. Ko) So is it strictly just new
16 products that you've done ROI-type activities for, or
17 have you done any ROI type of activity in connection
18 with products that are already on the market or you're
19 already selling or manufacturing?

20 A. I have only done ROI analysis on new
21 product or new business development opportunities.

22 Q. And how about Mallinckrodt in general? Do
23 they do ROI-type analysis on ongoing prescription
24 opioids that they sell and manufacture?

1 A. Mallinckrodt does return on investment
2 analysis for activities such as capital projects,
3 capital investment in order to understand the potential
4 return on those investments to the extent that they
5 support manufacturing.

6 Q. Do you know whether or not -- I know you
7 have some experience working in the specialty generics
8 space as you just indicated in your current role, and I
9 think -- I believe you've been in the generic space,
10 for lack of a better term, in the past. Does
11 Mallinckrodt provide any ROI-type activities on its
12 generic portfolio?

13 A. Again, we don't perform ROI activities on
14 the portfolio per se. We do perform ROI activities on
15 new opportunity analysis, future looking, or on capital
16 investment analysis.

17 Q. So generally speaking, the ROI-type
18 analysis that both you do and the company does is
19 dedicated to the new opportunities and
20 future-looking-type investments?

21 A. Generally that's correct, yes.

22 Q. Further down in your LinkedIn résumé, you
23 describe one of your skills as being data-driven
24 decision-making. Do you see that?

1 A. Yes.

2 Q. And that's one phrase this time; correct?

3 A. That is correct.

4 Q. And what do you mean -- can you explain to
5 the court what you mean by data-driven decision-making?

6 A. That's a reflection of making decisions
7 based upon an analysis of specific data, as opposed to
8 solely based on strategic factors.

9 Q. And why is that generally important for a
10 company like Mallinckrodt to utilize data-driven
11 decision-making?

12 A. Again, Mallinckrodt is a for-profit
13 business, and as such we want to make sure that our
14 decisions are made with an eye on profit and with an
15 eye on proper expenditure.

16 Q. And is it just profit and proper
17 expenditure that -- I know we're speaking in general
18 terms, so -- but in terms of other categories that
19 impact the decisions that you make, is it simply just
20 profit and expenditure, or are there other things that
21 a company like Mallinckrodt looks at?

22 A. We analyze many different sources of data
23 for many different reasons. As a product manager and
24 generally in product management, we will look at

1 data-driven decisions around forecasting future
2 production needs, around understanding price and other
3 market factors, and so it's not just relative to profit
4 but relative to other decisions that will drive the
5 business.

6 Q. And when you speak about market factors,
7 is it typical for Mallinckrodt with respect to a
8 product or products or a portfolio of products to do
9 some sort of SWOT analysis with respect to that product
10 or portfolio?

11 A. It is not routine, but we have
12 occasionally used SWOT analysis.

13 Q. And by SWOT, you understand that I'm
14 talking about strengths, weaknesses, opportunities, and
15 threats?

16 A. Yes.

17 Q. And when you say it's not routine, are you
18 saying that it's not the norm for Mallinckrodt to do a
19 SWOT analysis with respect to its products or a
20 portfolio of products?

21 A. We do not routinely conduct SWOT analysis
22 as a normal part of ongoing business.

23 Q. And do you know why that's the case?

24 A. That's not a tool that we have chosen to

1 implement as an across-the-board routine tool.

2 Q. But you have done -- well, would you say
3 in your experience at Mallinckrodt -- have you done
4 SWOT analyses with respect to the opioid products that
5 Mallinckrodt manufactures?

6 A. I cannot recall a specific SWOT analysis
7 relative to any opioid products.

8 Q. Fair enough. Going back to your
9 experience in the generic sector, I know right now you
10 said you've been in this role that you described to the
11 court for about a year and eight months. You have
12 previous experience in the specialty generics portion
13 of the business; is that fair to say?

14 A. Yes, that's correct.

15 Q. And how long is that experience?

16 A. So currently I have been in the specialty
17 generics business unit since late 2011 continuously in
18 various different roles. Prior to that time I spent
19 about four years in our portfolio management and
20 strategy group, during which time some of my activities
21 were devoted to the generics business. Prior to that I
22 spent about three years in the generics marketing group
23 in analytical roles.

24 Q. That's helpful. Thank you. And with

1 respect to Mallinckrodt's generic business,
2 approximately how many generic prescription opioids
3 does Mallinckrodt manufacture?

4 A. We manufacture about a dozen different
5 products in various different strengths and dosage
6 forms.

7 Q. And is oxycodone -- the generic version of
8 oxycodone one of the types of drugs that Mallinckrodt
9 manufactures?

10 A. Yes, it is.

11 Q. And in the dosage of 15 milligrams and 30
12 milligrams?

13 A. Yes, that's correct.

14 Q. Are there any other milligrams -- or any
15 other dosages that Mallinckrodt manufactures with
16 respect to generic oxycodone?

17 A. With respect to generic oxycodone tablets,
18 we manufacture a five-milligram tablet as well.

19 Q. And is it fair to say that the generic
20 version of the oxycodone, both in the 15-milligram and
21 the 30-milligram version -- are those your
22 bestselling -- are those Mallinckrodt's bestselling
23 generic drugs?

24 A. It depends on I guess how you would define

1 bestselling. They are not our largest drugs either in
2 volume or in sales dollars.

3 Q. Let's take sales dollars and revenue,
4 then. Was there any point in time from 2000 through
5 two thousand -- to present which in oxy 15 and oxy 30,
6 I'll call them for lack of a better term, were the
7 highest revenue-producing drug at Mallinckrodt -- for
8 Mallinckrodt? Excuse me.

9 A. I do not have the specific numbers in
10 front of me. I can't speak to that from memory.

11 Q. Is it fair to say that Mallinckrodt
12 derives substantial revenue from the sale and
13 manufacture of oxy 15 and 30s?

14 A. I would not say that we currently derive
15 substantial revenue from those products, no.

16 Q. How about in the 2005 through 2010 time
17 period? Would it be fair to say that Mallinckrodt
18 derived a substantial amount of revenue from the sale
19 and manufacture of oxy 15s and oxy 30s?

20 A. During that time, oxycodone tablets would
21 have comprised a larger portion of our portfolio in
22 revenue.

23 Q. And when you say larger portion --
24 relative to other drugs?

1 A. Relative to other drugs and our entire
2 portfolio.

3 Q. And did Mallinckrodt also -- what other
4 major types of prescription opioids in a generic form
5 did -- or has Mallinckrodt manufactured during your
6 tenure there?

7 A. So Mallinckrodt has manufactured
8 hydrocodone with acetaminophen combination tablets,
9 oxycodone with acetaminophen combination tablets,
10 morphine extended release tablets, methadone immediate
11 release tablets, hydromorphone release tablets. And
12 there are others.

13 Q. And when did Mallinckrodt get into the
14 generic space? In other words --

15 A. Uh-huh.

16 Q. -- when was the first year that
17 Mallinckrodt manufactured a generic version of an
18 opioid?

19 A. Mallinckrodt first manufactured generic
20 opioids in approximately 1995 or 1996.

21 Q. Which version was that?

22 A. I don't recall specifically what the first
23 product was that we manufactured.

24 Q. When did Mallinckrodt first manufacture

1 the generic version of oxycodone?

2 A. I don't know the exact year.

3 Q. Was it early 2000s, approximately
4 speaking?

5 A. Early 2000s is approximately correct.

6 Q. And then how about the generic version of
7 that hydrocodone with acetaminophen? When did
8 Mallinckrodt first manufacture that generic version?

9 A. That was one of our first products. That
10 would have been in or around 1995 or 1996.

11 Q. And then how about with respect to
12 hydromorphone with acetaminophen? When did that
13 first -- when did Mallinckrodt first manufacture that
14 generic version?

15 A. We do not manufacture hydromorphone with
16 acetaminophen.

17 Q. I'm sorry. I think I misheard you. When
18 did Mallinckrodt first manufacture the oxycodone with
19 acetaminophen generic version?

20 A. Yes. That was another one of our first
21 products. That would have also been sometime in the
22 late 1990s. 1995, 1996. Near that time.

23 Q. And then with respect to the generic
24 version of the methadone immediate release tablets,

1 when did Mallinckrodt first manufacture that generic
2 version?

3 A. Mallinckrodt has been manufacturing those
4 tablets for -- well, I don't know exactly. Since the
5 early 2000s, I believe.

6 Q. Going back to -- just real quickly, going
7 back to KV Exhibit 3, which is in front of you.

8 A. Uh-huh.

9 Q. It appears that you've spent your entire
10 career at Mallinckrodt. Is that correct?

11 A. That's correct.

12 Q. And before you joined Mallinckrodt -- or
13 excuse me. You joined Mallinckrodt right after you
14 graduated from Bradley university. Is that correct?

15 A. That's correct.

16 Q. And you -- I also see that you have an MBA
17 from Wash U here in St. Louis. And did you do that
18 while you were employed at Mallinckrodt?

19 A. Yes, I did.

20 Q. And did Mallinckrodt pay for that
21 schooling?

22 A. Mallinckrodt paid for part of that.

23 Q. Approximately how much?

24 A. Approximately a third.

1 Q. You can set that aside for now -- your KV
2 Exhibit 3. It probably makes sense to keep 1 and 2 in
3 front of you just to refer to.

4 A. Okay.

5 Q. Can you describe to the court what your
6 understanding of a chargeback is?

7 A. A chargeback is a financial transaction
8 which reconciles the difference between the acquisition
9 cost that a wholesaler pays for a product and the
10 contracted price that has been negotiated with the
11 manufacturer.

12 Q. And is it just the wholesaler that's
13 involved, or can there another entity that is subject
14 to a chargeback?

15 A. To my knowledge, chargebacks are only used
16 with wholesalers or distributors.

17 Q. And referring back to KV Exhibit 2, it
18 indicates that for purposes of Topic 12, which relates
19 to chargebacks, among other things, you didn't review
20 any materials, but you're testifying about this topic
21 based on your own personal knowledge and that's it; is
22 that correct?

23 A. That is correct.

24 Q. Did Mallinckrodt maintain chargeback data?

1 A. I'm not clear on what you mean by
2 maintain.

3 Q. Did Mallinckrodt have and/or possess any
4 chargeback data from distributors?

5 A. Mallinckrodt receives chargeback claims
6 from distributors and processes those claims.

7 Q. And do you know if Mallinckrodt obtains
8 chargeback data from any other entity other than
9 wholesale distributors?

10 A. I'm not aware of any other entity.

11 Q. Do you have an understanding of what this
12 chargeback data consists of?

13 A. In general terms, yes.

14 Q. And what does it consist of?

15 A. When a wholesaler submits a claim for a
16 chargeback, they provide us with the volume of product
17 sold by contract and the contract price associated with
18 each of those sales.

19 Q. And in connection with this claim, does
20 the wholesaler also provide information about the
21 downstream customer that has purchased the product from
22 the distributor?

23 A. The wholesalers provide some amount of
24 limited data about their downstream customer.

1 Q. And when you say limited, what do you mean
2 by that?

3 A. It varies depending upon the wholesaler or
4 the customer, and it could consist of information
5 relative to the identity of the customer purchasing the
6 product from the wholesaler, or in some cases it's --
7 no information is provided other than the contract
8 number.

9 Q. And when you say it varies, does it vary
10 because the terms of the contracts between Mallinckrodt
11 and the distributor are all different, or does it vary
12 between distributors just decide what to provide to
13 you -- to Mallinckrodt? Excuse me.

14 A. Both of those characterizations are
15 generally correct. The different wholesalers have
16 different policies for how they provide data and
17 different pharmacy customers for those wholesalers have
18 different policies about confidentiality and about the
19 amount of information that can be disclosed.

20 Q. I know you -- in connection with Exhibit 2
21 you said that you're just testifying based on personal
22 knowledge, but over your career at Mallinckrodt have
23 you seen -- have you personally seen chargeback data or
24 files that reveal chargeback information?

1 A. I have seen files that contain chargeback
2 information, yes.

3 Q. And do some of those files contain
4 information about the customer that purchases
5 Mallinckrodt opioids from distributors?

6 A. The files that I have seen -- some of them
7 do contain aggregated or consolidated data about the
8 pharmacy customers.

9 Q. And do they also contain information about
10 the quantity of pills that were purchased?

11 A. The chargeback data presents package
12 quantity, so for each individual product, the number of
13 packages that were sold has to be reported.

14 Q. And can you describe to the court what you
15 mean by package?

16 A. The smallest selling unit of product is
17 how we price product and how it's quantified in sales
18 transactions. That is usually, always in our case, a
19 bottle or box of tablets, capsules, or whatever the
20 dosage form is, so one package contains multiple
21 individual doses.

22 Q. I see. And do the -- does the chargeback
23 information that you reviewed in the past -- does it
24 also contain information about the dollar amount of the

1 transaction between the distributor and the purchaser
2 of the Mallinckrodt opioids?

3 A. No, it does not.

4 Q. You've never seen a chargeback sheet or
5 file or any kind of data that reveals the purchase
6 price between the distributor and the end user?

7 A. No, I have not.

8 Q. A moment ago you had described that your
9 understanding of a chargeback was that it represented
10 the difference between -- or it represented some
11 different amount between the distributor and the end
12 user on one hand and the purchase price between
13 Mallinckrodt and the distributor on the other. Was
14 that a fair characterization of what you said
15 previously?

16 A. I need to --

17 Q. Why don't we do it this way?

18 A. I need to make sure I unders -- I know
19 exactly which words you're using. Let me restate.

20 Q. Sure.

21 A. The -- a chargeback represents the
22 difference between the agreed-upon contract price that
23 applies to a given sale from a wholesaler to a pharmacy
24 or a pharmacy chain and the acquisition cost that

1 wholesaler purchases the product from Mallinckrodt.

2 Q. And with respect to the acquisition cost,
3 that is a cost agreed upon between the wholesaler and
4 Mallinckrodt; correct?

5 A. The acquisition cost is effectively a list
6 price set by Mallinckrodt that is not negotiated. It's
7 a set price.

8 Q. That is either accepted or not accepted by
9 a wholesale distributor?

10 A. It's a price that is set by Mallinckrodt.
11 There's no negotiation.

12 Q. Right. Fair enough. So given your
13 understanding that a chargeback represents the
14 difference between the agreed-upon contract price that
15 applies to a given sale from a wholesaler to a
16 pharmacy, is it my understanding -- or am I correct
17 that you previously testified a moment ago that the
18 chargeback information you revealed did not reflect
19 that price?

20 A. The --

21 Q. Or those prices? Sorry.

22 A. The chargeback information that we receive
23 does not with certainty reflect the price actually
24 sold -- that the product was actually sold to the

1 pharmacy. It reflects the contracted price between
2 Mallinckrodt and the wholesaler or Mallinckrodt and the
3 pharmacy chain that constitutes the chargeback owed on
4 that sale.

5 If a wholesaler negotiates something
6 separately with a pharmacy to either provide a higher
7 or lower price and sell the product at a different
8 price than the contract, that's within their rights in
9 managing their business. We are contractually
10 obligated to pay the chargeback amount on those sales
11 regardless of the selling price that the wholesaler
12 sold it at.

13 Q. I see. And when a moment ago you said
14 that the chargeback information does not reflect with
15 certainty the price that the drug was actually sold,
16 what do you mean by that?

17 A. For some contracts administered by the
18 wholesalers, those are contracts that Mallinckrodt has
19 entered into with a pharmacy chain for the acquisition
20 cost that that pharmacy is guaranteed from
21 Mallinckrodt. That sale from the wholesaler to that
22 pharmacy chain should occur at that price, but we don't
23 have visibility to the actual price charged.

24 Q. So your testimony is today that

1 Mallinckrodt never had any visibility to the actual
2 price that was charged between the distributor and the
3 downstream customer?

4 A. To my knowledge that's correct.

5 Q. And were chargebacks and/or chargeback
6 provisions contained in agreements between Mallinckrodt
7 and distributors with respect to the sale of generic
8 opioids that Mallinckrodt manufactured?

9 A. So our agreements with wholesalers and
10 distributors define the terms around chargebacks, and
11 they apply broadly to our entire generics portfolio,
12 whether it's opioid products or non-opioid products.

13 Q. Okay. So in other words -- if they apply
14 broadly, did you -- well, let's take a step back. Did
15 Mallinckrodt have any chargeback provisions with
16 distributors with respect to branded opioids that
17 Mallinckrodt manufactured and sold?

18 A. It is my understanding that some branded
19 contracts did have chargebacks.

20 Q. And process question. When Mallinckrodt
21 obtained some of this chargeback information, do you
22 know how your company stored or housed this data and
23 information? In other words, was it put into a central
24 repository or database?

1 A. Generally the detailed sales data that was
2 received from wholesalers was processed through a
3 database -- the specific database has changed over
4 time -- and the rebate claim was processed through our
5 rebates processing team, and so -- and our rebates
6 processing system would also have information about the
7 chargeback transactions.

8 Q. And with respect to the database or
9 databases that have been utilized to house this
10 information, do you know which databases those are?

11 A. The -- over time the databases have
12 changed. Our data warehouse, which we access through a
13 tool called Cognos, has contained that data over time,
14 as well as our pricing and rebate system, Model N. And
15 we also use a third-party aggregator to summarize some
16 of the information.

17 Q. And is that third -- what's the identity
18 of that third-party aggregator?

19 A. That's ValueCentric.

20 Q. Do you use the database J.D. Edwards at
21 all in connection with housing or maintaining
22 chargeback data?

23 A. Yes, I believe the invoices for
24 chargebacks are processed through J.D. Edwards.

1 Q. And has that been the case over time that
2 you've been there?

3 A. To my knowledge, that's been the case for
4 quite a while. I don't know exactly when we started
5 that.

6 Q. Going back to your testimony a moment ago
7 when you said that there was a rebates claim processing
8 team. First of all, what's your understanding of the
9 difference between a rebate and a chargeback?

10 A. So a chargeback is a financial mechanism
11 to reconcile the difference between acquisition cost
12 and contract price. A rebate is an additional discount
13 that is offered after sale and contingent upon sale but
14 can vary by customer or by contract.

15 Q. And when you said it's an additional
16 discount that is offered, offered to whom?
17 Distributors?

18 A. Primarily, yes, to distributors.

19 Q. And what other entities?

20 A. We have at times had rebate agreements in
21 place with pharmacy chains.

22 Q. And with respect to chargebacks, is it
23 also fair to say that the chargeback amounts that you
24 would pay, that Mallinckrodt would pay, were primarily

1 provided to distributors?

2 A. Yes, that's fair.

3 Q. And you said before you had no
4 understanding of any other entities that Mallinckrodt
5 may have provided chargeback amounts to?

6 A. That's correct.

7 Q. And in connection with chargebacks in
8 particular, is it fair to say that Mallinckrodt
9 provided substantial sums to these distributors in the
10 2007 through 2012 time frame?

11 MR. TSAI: Object to the form. Go ahead.

12 A. It depends upon the definition of
13 substantial, but the chargeback amount has at times or
14 can be, depending on the product, a fairly large amount
15 compared to the wholesale acquisition cost.

16 Q. (By Mr. Ko) And let's define -- can you
17 agree with me for purpose of this questioning that
18 substantial is defined as nine figures, so \$100 million
19 or more? Would you agree with me that Mallinckrodt has
20 paid amounts exceeding \$100 million in chargebacks to
21 distributors in the 2007 through 2012 time period?

22 A. Our chargeback payments during that time
23 period have been at least that much on occasion.

24 Q. And have they exceeded \$500 million in

1 some years?

2 A. I believe so.

3 Q. Have they gone up to \$700 million in some
4 years?

5 A. I'm not familiar with the numbers with
6 that level of specificity, no.

7 Q. And relative to the overall gross sales of
8 generic opioids, do the chargeback amounts represent at
9 least in some years a third to 40 percent of the total
10 gross sales figures?

11 A. If we define gross sales as total sales at
12 wholesale acquisition cost, then that is probably
13 correct, yes.

14 Q. Can you describe to the court why
15 Mallinckrodt was willing to pay such substantial
16 amounts in chargeback revenue to distributors?

17 A. Well --

18 MR. TSAI: Object to the form. Go ahead.

19 A. Thank you. There are a couple of
20 different reasons. Chargebacks, first of all, are an
21 industry standard, especially for generic drugs, and
22 chargebacks are a financial mechanism to again
23 reconcile between acquisition cost and a contract
24 price. The contract price is a pre-negotiated number

1 which the wholesalers and distributors understand and
2 Mallinckrodt understands is due to them -- the
3 difference is due to them on every sale they make.

4 We do not book revenue at gross sales,
5 understanding that that chargeback claim is always
6 going to be paid on every unit that they sell. The
7 wholesale acquisition cost is merely a way to provide
8 a consistent list price among all customers and the
9 chargeback is a way to deliver them financial value
10 based upon negotiated pricing.

11 Q. (By Mr. Ko) Is it fair to say that
12 Mallinckrodt had an interest in providing chargeback
13 amounts to distributors in order for the distributors
14 to continue distributing Mallinckrodt-manufactured
15 opioids?

16 A. It was in Mallinckrodt's interest to abide
17 by our contract commitments, and our contracts with the
18 distributors specified how and when we would pay
19 chargebacks.

20 Q. And aside from the contractual provisions,
21 as a marketing strategy -- from a marketing strategy
22 perspective or given your experience in product and
23 portfolio management, do you feel that it was important
24 for Mallinckrodt to continue paying chargeback amounts

1 in order to make sure that the distributors continued
2 distributing Mallinckrodt-manufactured opioids?

3 A. The chargeback is a financial mechanism.
4 It's a number that is created in order to make the
5 distributor whole compared to their acquisition cost
6 relative to the contract price that's been negotiated.
7 The sale is predicated upon that negotiated price. We
8 all understand that that price is the price for that
9 product, and the chargeback is merely a mechanism to
10 ensure that the numbers reconcile on both sides of the
11 transaction.

12 Q. Did you have any communications with
13 distributors or any representatives of wholesale
14 distributors with respect to the chargeback provisions
15 in any particular agreement that Mallinckrodt had with
16 these entities?

17 A. Answering on behalf of Mallinckrodt, yes,
18 Mallinckrodt does negotiate the terms of agreements,
19 including chargebacks.

20 Q. And who was primarily responsible for
21 that? In other words, what -- to the best of your
22 knowledge, what individuals or what department at
23 Mallinckrodt had that primarily -- primary
24 responsibility?

1 A. The primary responsibility for negotiating
2 contracts with our customers lies with the national
3 accounts team, and that national accounts team
4 negotiates specifics based upon approval of management.

5 Q. And who was the head or the heads of the
6 national account team at Mallinckrodt from, let's say,
7 the 2007 through 2012 time period?

8 MR. TSAI: I'll just note this is getting
9 I think away from his -- the witness's assigned topics,
10 but go ahead.

11 A. I have not prepared on the specific org
12 charts during those periods and can't recall exactly
13 who was in charge of the sales team during that time.

14 Q. (By Mr. Ko) Okay. I'm going to hand you
15 a copy of what's going to be marked as KV Exhibit 4.

16 [Exhibit Mallinckrodt-Vorderstrasse-004
17 marked for identification.]

18 Q. Kevin, do you recognize this agreement at
19 all? Or excuse me. Do you recognize this exhibit at
20 all?

21 A. I recognize what it is. I am not familiar
22 with the specific document.

23 Q. I will represent for the record that this
24 appears to be a supply policy agreement between Rite

1 Aid and Mallinckrodt that was entered into January 1,
2 2010, and signed on January 12th, 2010. Is that a fair
3 characterization of this document?

4 A. That appears to be correct, yes.

5 Q. And I believe I said January 10th, but I
6 think the agreement was signed on January 12th.

7 A. Yes.

8 Q. And for the record, KV Exhibit 4 begins at
9 MNK-T1_0000365268. So Rite Aid, as we all know, is a
10 pharmacy; correct?

11 A. Rite Aid is a pharmacy chain. That's
12 correct.

13 Q. And earlier you said that you were unaware
14 of any chargeback provisions between pharmacies and
15 Mallinckrodt. Do you remember that?

16 A. Yes.

17 Q. Can you turn to Page 3 of this document
18 and Paragraph 10? At Paragraph 10A, the agreement
19 states weekly generic chargebacks, Rite Aid and vendor,
20 vendor being Mallinckrodt, agree to the terms of the
21 weekly generic chargebacks as described in Exhibit 4.
22 Do you see that?

23 A. I do.

24 Q. So this appears to be an agreement that

1 Mallinckrodt had with a pharmacy chain regarding
2 chargebacks; is that fair?

3 A. That appears to be, yes.

4 Q. But you had no personal knowledge coming
5 into this deposition that Mallinckrodt had such
6 agreements with pharmacies; is that correct?

7 A. That's correct.

8 Q. And if we fast-forward to Exhibit 4 of
9 this agreement, that is the Exhibit 4 that's referenced
10 in the Section 10A that we just looked at; is that
11 correct?

12 A. Yes, I believe so.

13 Q. And there are some details about the
14 weekly generic chargeback that Rite Aid and
15 Mallinckrodt are agreeing to; is that correct?

16 A. Yes, it appears to be.

17 Q. And at the bottom -- well, there are
18 various provisions and terms in this exhibit, but at
19 the bottom of that exhibit, the last paragraph -- why
20 don't you go ahead and read that last paragraph and let
21 me know when you're done?

22 A. Okay.

23 MR. TSAI: David, we've been going over an
24 hour now. Is -- after we're done with this exhibit,

1 can we take a quick break?

2 MR. KO: Sure.

3 A. Okay. I understand what this is.

4 Q. (By Mr. Ko) Okay. So based on that last
5 paragraph that you read, would it be fair to say that
6 Rite Aid was providing some information to Mallinckrodt
7 in connection with the chargeback provisions contained
8 in this agreement? Is that a fair characterization?

9 A. It appears that they were, yes.

10 Q. And this report in terms of frequency --
11 it was weekly; is that correct?

12 A. That's what it states, yes.

13 Q. And the information comprised -- the
14 information provided by Rite Aid to Mallinckrodt was
15 the result of an EDI feed. Does that sound familiar to
16 you at all or do you know what that's referring to?

17 A. I am familiar with what an EDI feed is,
18 yes.

19 Q. And what is your understanding of an EDI
20 feed?

21 A. An EDI feed is electronic data shared
22 between trading partners under an established standard
23 for exchanging transaction information or other
24 details.

1 Q. And details of what in this -- in the
2 context of how you've seen it?

3 A. Primarily EDI data that we use as a
4 pharmaceutical manufacturer consists of wholesaler
5 inventory data or wholesaler sales data.

6 Q. And sales data reflecting the sales
7 between in this case a pharmacy and some downstream
8 customer? Is that a fair characterization?

9 A. In this case, the document states that the
10 EDI feed will be from Rite Aid's wholesalers --
11 wholesaler showing purchases of product by Rite Aid.

12 Q. And so -- and presumably Rite Aid's
13 wholesaler here is referring to a distributor; correct?

14 A. Yes, generally the wholesaler and
15 distributor are used interchangeably.

16 Q. And so in this context it appears that
17 Rite Aid is providing some information from its
18 wholesaler and transferring that to Mallinckrodt
19 through this EDI feed?

20 A. I read this to say that the wholesaler was
21 providing information about their sales to Rite Aid.

22 Q. And Rite Aid would subsequently transfer
23 that information to Mallinckrodt; correct?

24 A. I don't read this as Rite Aid transferring

1 the information.

2 Q. In the third sentence it says a weekly
3 report listing these purchases will be provided by Rite
4 Aid to vendor. Do you see that? Did I read that
5 correctly?

6 A. Yes.

7 Q. And then the next sentence goes on to say
8 the transactions on this report will be the result of
9 an EDI feed from Rite Aid's wholesaler showing these
10 purchases of product. Did I read that correctly?

11 A. That is correct.

12 Q. So in this context it does appear that the
13 distributor is providing information to Rite Aid who
14 was then transferring that information over to
15 Mallinckrodt?

16 A. In the general term of information, yes.
17 The EDI feed is -- I read is different from the weekly
18 report.

19 Q. Fair enough, but the original source of
20 this information which pertains to purchases of
21 product, as this contract suggests, comes from the
22 wholesaler and then that information is transferred
23 over to Mallinckrodt; is that fair?

24 A. Yes, that's fair.

1 Q. And I know you said that you've never seen
2 one of these or have any experience understanding an
3 agreement containing a chargeback provision between
4 Rite Aid -- or a pharmacy and Mallinckrodt, but it
5 appears here in this paragraph that there are certainly
6 amounts that Mallinckrodt is willing to pay to a
7 pharmacy with respect to chargebacks; is that fair?

8 A. The way I would characterize this is that
9 this is a different use of the term chargeback.
10 Chargeback is a collective term which generally
11 speaking means a reversal or a return of value to a
12 customer. In this case, the process that's being
13 described is an instance where we had a negotiated
14 price with Rite Aid for the purchase of product on a
15 direct basis, but where they purchased product
16 indirectly for that given product at a higher price
17 from a wholesaler, and we would make them whole to
18 their direct price pre-negotiated with us on those
19 transactions.

20 So in the context of the typical use of
21 the term chargeback, we in Mallinckrodt would not
22 typically call this type of transaction a chargeback.
23 We would call this a cost differential agreement
24 similar to the kind of subtitle of this exhibit.

1 Q. Nevertheless, this is an agreement titled
2 weekly generic chargeback, generic cost differential,
3 and at least as agreed upon between Mallinckrodt and
4 Rite Aid, this appears to be an agreement containing
5 chargeback amounts or provisions that Mallinckrodt is
6 willing to pay to a pharmacy in connection with the
7 distribution of Mallinckrodt opioids; is that fair?

8 A. This exhibit defines the process whereby
9 Mallinckrodt makes whole the customer to provide them
10 the value that we've negotiated in advance that they
11 are eligible on every purchase.

12 Q. And let me stop you right there. By
13 customer we're talking about -- just so we're on the
14 same page, we're talking about Rite Aid here?

15 A. In this case the customer was Rite Aid
16 pharmacy chain.

17 Q. Correct. Okay. So Mallinckrodt is paying
18 a pharmacy chain an amount to, as you said, make them
19 whole pursuant to some sort of agreement to distribute
20 drugs; is that fair?

21 A. We have agreed upon a purchase price for
22 Rite Aid for products -- for Mallinckrodt products.
23 This Exhibit and this agreement provides a mechanism
24 for us to ensure that they are able to purchase the

1 price at that -- or purchase the product at that
2 pre-agreed price.

3 Q. And I want to fast-forward before -- I
4 want to honor Rocky's request for a break to do, but
5 just real quickly, turn back to the beginning of the
6 document at Page -- the first page in Section 2B. You
7 see where it says, no later than 90 days from the date
8 of the first purchase order issued by Rite Aid to
9 vendor, vendor being Mallinckrodt, Mallinckrodt must
10 have EDI capability to exchange purchase orders,
11 invoices, and advance shipment notices electronically
12 in accordance with Rite Aid specifications at a
13 minimum -- at minimum. Did I read that correctly?

14 A. Yes, you did.

15 Q. And so there's another reference here to
16 EDI capability, and it appears that Rite Aid is
17 imposing some sort of requirements upon how the EDI
18 information is going to be transmitted to Mallinckrodt.
19 Is that fair?

20 A. What Rite Aid is asking for here is
21 industry standard electronic data exchange around
22 orders.

23 Q. And when you say industry standard, I just
24 want to make sure I understand what you're saying.

1 Industry standard in the context of agreements between
2 pharmacies, or industry standard in the context of
3 agreements between distributors, or both?

4 MR. TSAI: If I could just make a scope
5 objection just for the record. So Topic 12 relating to
6 chargebacks is limited to, as written, with any
7 pharmacy in a CT1 jurisdiction and/or manufacturer of
8 controlled substances distributed in a CT1
9 jurisdiction. With that objection, you can answer.

10 A. So in the pharmaceutical industry,
11 exchanges of order information between a manufacturer
12 and a purchasing warehouse often are conducted
13 electronically. There are specific EDI standards for
14 that electronic data interchange, and at the time of
15 this agreement, Rite Aid purchased at least many of the
16 products from Mallinckrodt on a direct basis into their
17 warehouse to distribute to their pharmacies. That
18 clause, to be, states that they expect within 90 days
19 that we can accomplish those transactions
20 electronically.

21 MR. KO: Thank you for that answer, and
22 I'll also note for the record that Rite Aid is a
23 pharmacy in a CT1 jurisdiction. And with that we can
24 take a break.

1 THE VIDEOGRAPHER: We are going off the
2 record at 10:25 AM.

3 [A brief recess was taken.]

4 THE VIDEOGRAPHER: We are back on the
5 record at 10:39 AM.

6 Q. (By Mr. Ko) And Kevin, welcome back from
7 the break. Earlier you were testifying with respect to
8 chargeback agreements and rebate arrangements that
9 Mallinckrodt had with various entities. Can you
10 generally describe to the court your awareness of any
11 other types of incentive programs that Mallinckrodt had
12 with either distributors or pharmacies?

13 MR. TSAI: Object to the form. Go ahead.

14 A. So Mallinckrodt generally has agreements
15 with wholesalers which specify the fees for service
16 that we pay those wholesalers to distribute our
17 products, and the wholesalers also provide generic
18 sourcing programs to their pharmacy customers. Those
19 sourcing programs have contracts with Mallinckrodt
20 which specify a negotiated contract price and any other
21 rebates or discounts for those sales.

22 In addition, we had similar contracts with
23 pharmacy wholes -- or pharmacy chains where we would
24 negotiate a price with them either for their direct

1 purchase of product into their warehouses for
2 distribution to their pharmacies or a contracted price
3 that they were guaranteeing when purchasing through a
4 wholesaler.

5 Q. (By Mr. Ko) And in connection with
6 Mallinckrodt's sale and manufacture of its opioid
7 products, did it also have any agreements with pharmacy
8 benefit managers?

9 A. No, not for generic products.

10 Q. Do you know whether or not -- strike that.
11 So with respect to its branded products, do you know
12 whether or not Mallinckrodt had agreements with
13 pharmacy benefit managers with respect to
14 Mallinckrodt-branded opioids?

15 A. Yes, we did.

16 Q. And which PB -- which pharmacy benefit
17 managers, which I'll call PBMs?

18 A. I do not know specifically which PBMs we
19 had agreements with for the branded products.

20 Q. Do you know who at Mallinckrodt would be
21 in charge of -- or what departments would be in charge
22 of the agreements Mallinckrodt had between -- or had
23 with PBMs with respect to branded opioids products
24 Mallinckrodt manufactured?

1 A. At that time the market access team as
2 part of the brand business would have been responsible
3 for those contracts. That team no longer exists.

4 Q. And when you say at that time, what time
5 are you referring to?

6 A. During the time period that we marketed
7 branded opioids. Our last branded opioid we ceased
8 marketing in around the 2015 time period.

9 Q. And which -- for the record, which branded
10 opioid was that?

11 A. The last one was Xartemis XR.

12 Q. And that is -- I've referred to is as
13 "Xart-emis," but you said it as --

14 A. "Xar-temis" XR.

15 Q. "Xar-temis." Okay. That's helpful to
16 know. And by the way, when was -- when did
17 Mallinckrodt stop marketing Exalgo?

18 A. Exalgo I believe we stopped marketing in
19 2014.

20 Q. And just to actually round out the time
21 periods, when did Mallinckrodt begin marketing Exalgo?

22 A. I don't know the exact date. It's on or
23 around 2009, I believe.

24 Q. And the same question with respect to

1 "Xart-emis." Can you say it again?

2 A. "Xar-temis."

3 Q. "Xar-temis."

4 A. We began marketing that in 2014.

5 Q. And then you pulled it off in 2014 as
6 well, so it only lasted for a year? Is that what
7 you're saying?

8 A. That's correct.

9 Q. Going back to KV Exhibit 2. We had a
10 discussion earlier this morning off the record about
11 some of the things that were contained in it, but there
12 is a response. Do you see the response column that's
13 provided in this exhibit?

14 A. Yes, I see that.

15 Q. And it appears that there is -- we were
16 provided this document for the record, but it appears
17 that there is a response to the topic that you are
18 being designated to testify on. Is that a fair
19 characterization of that column?

20 A. That column summarizes the general
21 response that I'm prepared to talk to.

22 Q. And can we incorporate by reference in
23 your testimony today all these responses? Are you
24 comfortable doing that?

1 A. Yes.

2 Q. So in other words, the responses contained
3 in this document accurately reflect the responses you
4 would give in response to these topics?

5 A. That's correct.

6 Q. Do you know what 867 data is?

7 A. Yes, 867 data is a -- is one of the EDI
8 standards that is related to sales data from
9 wholesalers to their pharmacy customers.

10 Q. So is it strictly regulated -- in other
11 words, it's sales data between wholesalers and pharmacy
12 customers as far as your understanding?

13 A. As far as my understanding, the primary
14 purpose of 867 data is to document information about a
15 transaction between a wholesaler and its customer. In
16 this case, that would be pharmacies.

17 Q. And what do you mean by in this case?

18 A. EDI 867 is a broad standard that can be
19 used in any number of industries. It's a general data
20 standard for electronic data interchange between
21 trading partners. It could be used in other industries
22 beyond pharmaceuticals.

23 Q. Understood, but just so I'm clear, 867
24 data could reveal more sales data than just between

1 wholesalers and pharmacies; correct? It could also
2 include wholesalers and other downstream purchasers of
3 pharmaceuticals?

4 A. I would be speculating as to what the
5 identity of those purchasers would be. My
6 understanding is that wholesalers sell their product to
7 pharmacies.

8 Q. And by the way, for the record, what
9 does -- what is your understanding of what EDI stands
10 for?

11 A. Electronic data interchange.

12 Q. And was that an actual third-party vendor
13 that housed this type of data -- like in other words,
14 an actually entity called EDI, or is it a term of art
15 in the industry?

16 A. So my understanding is that EDI is the
17 acronym used for the data interchange standard. There
18 is a third party, a governing body, if you will,
19 industry association that handles data standards. I'm
20 not familiar with the exact name of that organization,
21 but they specify these types of data standards.

22 Q. And did Mallinckrodt purchase -- ever
23 purchase 867 data?

24 A. We have agreements with our wholesalers

1 and distributors for -- to pay them fees for service
2 provided. One of those services that they provide is
3 to provide data on their sales transactions and on
4 their inventory.

5 Q. And that data is 867 data?

6 A. Among other pieces of data, yes.

7 Q. Fair enough. Fair enough. So
8 Mallinckrodt didn't directly purchase the 867 data from
9 a third-party vendor, but acquired the data directly
10 from distributors or other entities pursuant to the
11 contracts Mallinckrodt had with those entities?

12 A. Distributors and wholesalers provide the
13 data feed for EDI 867, yes.

14 Q. To Mallinckrodt; correct?

15 A. To Mallinckrodt.

16 Q. And what is 852 data?

17 A. Similarly, 852 data is a defined data
18 standard relative to understanding inventory and
19 movement of inventory within a wholesaler's
20 distribution network. It allows us to see the quantity
21 of our products which are in stock at a given
22 distribution center of a wholesaler. Gives us general
23 information about the quantities being moved throughout
24 their network or the quantities that they have on

1 order.

2 Q. And similar to the 867 data, did
3 Mallinckrodt also acquire 852 data from wholesalers?

4 A. 852 data was provided to us from our
5 wholesalers as part of our fee-for-service agreements.

6 Q. So just so the record is clear, if
7 pursuant to the fee-for-service agreements there was a
8 provision for the acquisition of 852 and 867 data,
9 Mallinckrodt was provided this information from a
10 distributor; correct?

11 A. 852 and 867 data is provided to us from
12 our distributors -- those that provide it. Some
13 distributors do not provide that data, but it is all
14 covered in our agreements with those distributors.

15 Q. And do you have a general understanding of
16 what time period -- or strike that. Do you know when
17 Mallinckrodt first started obtaining either 852 or 867
18 data from distributors?

19 A. No, I'm not familiar with when we began
20 obtaining that data.

21 Q. Do you have a general understanding of
22 whether or not that was before the 2010 time period?

23 A. Yes, it was prior to 2010.

24 Q. Was it sometime between 2000 and 2010?

1 A. Possibly. I can't say for sure if it was
2 before or after 2000.

3 Q. And who at Mallinckrodt would be
4 responsible for managing or administering the
5 acquisition of 852 or 867 data from a distributor?

6 A. So a number of different groups would have
7 been involved. Again, the national accounts team would
8 have been involved in negotiating the agreements. The
9 finance team or the product management team would have
10 been involved in the decision to ask for such data from
11 the wholesaler or distributor, and then our information
12 technology, IT department, would have been responsible
13 for receiving the data and processing it into our data
14 warehouse.

15 Q. Okay, that's helpful. Thank you. So
16 you're part of the product management team now and have
17 been in the past; correct?

18 A. Correct.

19 Q. And when you say that the product
20 management team would be involved in the decision to
21 acquire such data -- what were some of the reasons that
22 Mallinckrodt would decide to acquire this data?

23 A. So I can't speak to that specifically.
24 Those decisions would have been made a very long time

1 ago, and I'm not aware of any documents that documented
2 how that decision was made.

3 Q. When you say that they were made a very
4 long time ago, are you saying that it was a business
5 decision by someone at Mallinckrodt that seems to be a
6 business practice over time that you simply abided by?

7 A. We have acquired 867 and 852 data for
8 quite some time, and that has been a part of our
9 agreements with our distributors for a very long time
10 and has not been changed since.

11 Q. Got it. And you are still acquiring 852
12 and 867 data currently?

13 A. That's correct.

14 Q. And are you acquiring 867 and 852 data
15 with respect to opioid products that Mallinckrodt
16 manufactures and sells?

17 A. We acquire those data for all of our
18 generic products.

19 Q. Including Mallinckrodt opioids?

20 A. Including -- yes, including Mallinckrodt
21 opioids.

22 Q. It's just important that we don't talk
23 over each other.

24 A. Sorry.

1 Q. That's okay. I want to hand you a copy of
2 what's going to be marked as KV Exhibit 5. It's an
3 e-mail with an attachment, so there's --

4 [Exhibit Mallinckrodt-Vorderstrasse-005
5 marked for identification.]

6 Q. I'm handing you -- the court reporter has
7 just handed you KV Exhibit 5, which is Bates-stamped
8 MNK-T1_0000387037, and is an e-mail exchange involving
9 among others Karen Harper and Bill Ratliff dated July
10 18th, 2007. Do you see that?

11 A. Yes, I do.

12 Q. And this e-mail also contains an
13 attachment. Do you see that?

14 A. Yes.

15 Q. Attachment is titled supply chain project,
16 IntegriChain. Have you ever heard of IntegriChain?

17 A. Yes, I have.

18 Q. What's your understanding of what
19 IntegriChain is?

20 A. My understanding of IntegriChain is that
21 they are a third-party data aggregator that aggregates
22 EDI data for pharmaceutical companies.

23 Q. And do you know whether or not
24 IntegriChain was -- did Mallinckrodt ever retain

1 IntegriChain at any time you were there for third-party
2 data aggregating purposes?

3 A. We did not retain IntegriChain for
4 aggregation purposes relative to the commercial use of
5 that data.

6 Q. Did you --

7 A. I can't speak to any other use we might
8 have contracted for.

9 Q. Fair enough. Going back to the e-mail,
10 who's your -- can you describe to the court who Karen
11 Harper is?

12 A. Karen Harper is our -- now director of DEA
13 compliance, at that time manager of DEA compliance.

14 Q. Do you work with her at all?

15 A. Yes.

16 Q. In what capacity?

17 A. General exchange of information relative
18 to DEA information, DEA issues, quota, things of that
19 nature.

20 Q. And how frequent would you describe your
21 communications with her? Daily? Weekly?

22 A. Monthly at best.

23 Q. Monthly at best? Okay. And who's Bill
24 Ratliff?

1 A. Bill Ratliff was our head of security at
2 the time. Not -- I'm not aware of what his exact title
3 was at that time.

4 Q. And do you have any communications with
5 Mr. Ratliff?

6 A. No.

7 Q. Have you ever had any communications with
8 him?

9 A. Not any more than just a passing hello.

10 Q. So I understand that IntegriChain was not
11 retained for commercial purposes of data aggregation as
12 you understand it, but this attachment contains kind of
13 a, for lack of a better term, general scope of work
14 that they would -- that they were pitching Mallinckrodt
15 for. Is that fair to say?

16 A. I have not reviewed the document yet.

17 Q. Why don't we take a look at the attachment
18 and look at the first sentence?

19 A. Okay.

20 Q. The title of this document says supply
21 chain project, IntegriChain, and the first sentence
22 says, in order to address the risks of abuse and
23 diversion at the pharmacy/patient level, we will need
24 better and further visibility into the supply chain.

1 Did I read that correctly?

2 MR. TSAI: I would object as to scope. We
3 have clearly delineated that Mr. Vorderstrasse is not
4 going to be testifying with respect to issues on
5 diversion, suspicious order monitoring, or DEA, CSA
6 compliance. You'll get the opportunity with another
7 one of our three designees to delve into those issues,
8 so I'll just note that objection.

9 MR. KO: And just to respond to that
10 objection, I understand the line that you're trying to
11 draw, Mr. Tsai, but the topics are much more broad and
12 expansive, as indicated in Exhibit -- KV Exhibits 1 and
13 2, and in this context it's very clear that Mr.
14 Vorderstrasse has been designated to speak on
15 information provided or received pertaining to 867 or
16 852 sales data, of which this refers to, so we will
17 continue to talk about this.

18 Q. (By Mr. Ko) And with that noted for the
19 record, Kevin, did I read that first sentence
20 correctly?

21 A. Yes, you did.

22 Q. And so it appears that IntegriChain is
23 approaching Mallinckrodt to present the ability to
24 access some data to better and further understand the

1 supply chain after Mallinckrodt manufactures a drug.

2 Is that a fair characterization?

3 A. Again, I haven't read the whole document,
4 but it appears that they are talking about industry
5 data.

6 Q. Industry data that will allow Mallinckrodt
7 to better and further understand visibility into the
8 supply chain; correct?

9 A. That is what they're claiming in the
10 background.

11 Q. Fair enough. And among the proprietary
12 tools that IntegriChain is suggesting that it has the
13 ability to do, it is basically saying, if you look
14 further down, that they can aggregate a large level of
15 various forms of data, as reflected by those bullets in
16 the middle of that page. Do you see that?

17 A. I see that section.

18 Q. And among the things that it is purporting
19 to do in the second-to-last bullet under the
20 proprietary tools section, it indicates that
21 IntegriChain has the ability to validate chargebacks
22 against 867 and fast non-retail save on audit fees. Do
23 you see that?

24 A. Yes, I do.

1 Q. Do you have any understanding of how
2 chargebacks can be validated against 867 sales data?

3 A. I am not clear on what they're proposing
4 to do.

5 Q. And separate and apart from what they may
6 have proposed to do, have you ever in your experience
7 or do you have any understanding of how Mallinckrodt
8 validates chargebacks against 867 data?

9 A. As part of our processing of chargebacks,
10 we do review 867 data to ensure that the quantities
11 reported as sold on 867 data total the quantities
12 provided on the chargeback invoice from the wholesaler
13 or distributor to ensure that the quantity or the
14 amount that they have submitted a claim for is
15 accurate.

16 Q. And so -- thank you. That's a very
17 helpful explanation. Is it fair to say then that the
18 867 data is a -- I guess is a check- or a
19 validation-type tool to use to ensure that the
20 chargeback amounts being paid to the distributors are
21 accurate?

22 A. We use 867 data to validate that the
23 quantities and prices submitted by the wholesalers are
24 accurate as represented in the 867 data.

1 Q. And just to confirm, the 867 sales data
2 has information regarding the sales price between a
3 distributor and a downstream customer of that
4 distributor; correct?

5 A. No, that's incorrect. The 867 data shows
6 the contract identification and the contracted price
7 that that sale is eligible for based upon
8 Mallinckrodt's negotiated price for those contracts.

9 Q. Thank you for that clarification. The --
10 so the contracted price as between whom?

11 A. The contracted price between Mallinckrodt
12 and the party which is responsible for that contract.
13 That party could be the wholesaler for the generic
14 sourcing program that they provide to their pharmacy
15 customers. It could be a contract that Mallinckrodt
16 has with a pharmacy chain or with a buying group or
17 other entity that represents pharmacies.

18 Q. That's helpful. Thank you. You can put
19 that aside. Do you know if Mallinckrodt ever had
20 arrangements with -- or strike that. Are you familiar
21 with the entity OptiSource?

22 A. Yes.

23 Q. And are you familiar with -- is it fair to
24 say that there's a buying group called OptiSource? Or

1 how would you -- why don't you describe to the court --

2 A. Yeah.

3 Q. -- what your understanding of OptiSource
4 is?

5 A. OptiSource is a contracting entity that
6 represents multiple regional distributors. That
7 distributor list that changed over time. OptiSource
8 conducts negotiations and contracting with generic
9 suppliers to secure contracted pricing for those
10 wholesale customers.

11 Q. And do you know whether -- thank you for
12 that explanation. Did -- were there any other entities
13 that represented multiple regional distributors that
14 Mallinckrodt had arrangements with for the manu -- for
15 the sale of Mallinckrodt opioid products?

16 MR. TSAI: Object to the form. Go ahead.

17 A. I'm trying to recall if there were other
18 specific entities which provided a similar contracting
19 service or contracting process with regional
20 distributors. I can't recall any specific ones at this
21 time.

22 Q. (By Mr. Ko) Is it your general
23 understanding that there may have been other entities
24 or buying groups other than OptiSource that

1 Mallinckrodt may have had arrangements with to sell its
2 opioid products?

3 A. We may have had other arrangements with
4 distributor buying groups similar to OptiSource from
5 time to time.

6 Q. And would these buying groups provide --
7 or strike that. Would there be any agreements or
8 provisions in the agreements between Mallinckrodt and
9 these buying groups that would contain provisions with
10 respect to chargebacks or 852 and 867 sales data?

11 A. Perhaps. These -- as distributors, these
12 would be entities that we had a fee-for-service
13 agreement with, and that may have included 852 or 867
14 data.

15 Q. So as you can see, I'm just trying to get
16 a general understanding of what other entities that
17 Mallinckrodt had agreements with other than
18 distributors for these fee-for-service agreements that
19 you're describing, and so in addition to distributors
20 and in addition to pharmacies, as we described earlier,
21 there were these buying groups that Mallinckrodt had
22 relationships with as well that represented regional
23 distributors, as you said. Is that correct?

24 A. We did have arrangements with regional

1 distributor groups, yes.

2 Q. And you had arrangements with regional
3 distributor groups that potentially contained
4 chargeback provisions and agreements to acquire 852 and
5 867 sales data; is that correct?

6 A. That is correct.

7 Q. With respect to the 867 data in
8 particular, do you know for the agreements in which
9 Mallinckrodt had such agreements in place to acquire
10 this data -- do you know the frequency of which they
11 were acquiring 867 data from a distributor?

12 A. So when we acquired 867 data, it was -- it
13 varied depending upon the distributor or depending upon
14 what time in the past, time period in the past when we
15 received that information. It could be as quickly as
16 within a day or two or it maybe lagged by weeks or even
17 a month.

18 Q. Do you know whether or not Mallinckrodt
19 obtained 867 data from Cardinal?

20 A. I can't say that with certainty.

21 Q. Do you have any understanding of whether
22 or not Mallinckrodt obtained 867 data from
23 AmerisourceBergen?

24 A. I believe so, yes.

1 Q. And how about with respect to McKesson?
2 Do you know whether or not Mallinckrodt obtained 867
3 data from McKesson?

4 A. Yes, I believe so.

5 Q. And do you have an understanding of how
6 frequent that data was provided? Let's start with
7 McKesson. Do you know how frequent the 867 data was
8 provided to Mallinckrodt by McKesson?

9 A. I don't know specifically throughout time
10 how often we've received that data. At various
11 different times it's been within a day or two with
12 McKesson.

13 Q. Generally speaking with respect to
14 distribut -- any distributor, what was the longest
15 period in which you recall the data being provided to
16 Mallinckrodt?

17 A. The longest period would have been about a
18 month.

19 Q. That's helpful. Do you know who Carol --
20 I might not be saying this correctly, but Carol
21 Svejkosky is?

22 A. Yes. Carol Svejkosky, I believe. I
23 believe she was in the finance department on the
24 branded team.

1 Q. Did you have any communications with
2 Carol?

3 A. Occasional communications over the years.

4 Q. And what were the nature of those
5 communications?

6 A. I don't recall specifically, but they
7 weren't routine communications.

8 Q. Sure. I'm going to hand you a copy of
9 what the court reporter will mark as KV Exhibit 6.

10 [Exhibit Mallinckrodt-Vorderstrasse-006
11 marked for identification.]

12 Q. For the record, KV Exhibit 6 is an e-mail
13 exchange involving multiple people at
14 Mallinckrodt/Covidien, and the first page of that
15 document is Bates-stamped MNK-T1_0005905464, and
16 appears to be an e-mail exchange dated -- titled EDI
17 867 transmissions, Cardinal request, and it is dated in
18 the March 9th, 2012, time period. Do you see that?

19 A. Yes.

20 Q. Feel free -- I have some pretty specific
21 questions based on this document, so feel free to
22 consult the whole thing if you need to, but hopefully
23 we can move things along by just asking and pointing
24 you to some specific areas. So first of all, if you

1 look at pa -- if you look at the second page of this
2 e-mail, there's an e-mail from Carol, and it appears
3 that she is the director of contracts and government
4 reporting. Do you see that?

5 A. Yes.

6 Q. And so I know earlier you said that she
7 was in finance and involved in generics. Does this
8 refresh your recollection at all that she was actually
9 also a director in contracts and government reporting?

10 A. Yes, somewhat. I do remember that she was
11 involved in government pricing issues at one point.

12 Q. And certainly this isn't a memory test of
13 every single person and what their titles were at
14 Mallinckrodt. I know there were a lot of employees
15 there. But in connection with Carol's role as a
16 director of contracts and government reporting, did you
17 have any communications with her, now that you see what
18 her role is in that position as director of contracts
19 and government reporting?

20 A. So in a personal capacity I may have had
21 some communications with her over time, but I don't
22 recall specific communications.

23 Q. Was there ever a time -- so with respect
24 to the 867 data, you had testified earlier -- and

1 correct me if I'm wrong -- but the 867 data was
2 acquired by Mallinckrodt in connection with the
3 manufacture of its opioid products; correct?

4 A. 867 data was acquired by Mallinckrodt in
5 connection with the sales of our generic products,
6 including opioids, from wholesalers or distributors to
7 their customers.

8 Q. And was -- did Mallinckrodt also obtain
9 867 data in connection with any other products it
10 manufactured other than its generic opioid products?

11 A. I am not aware if we obtained 867 data for
12 our branded products.

13 Q. And how about any other product that
14 Mallinckrodt manufactures in sales, including
15 non-opioids? Do you know whether or not Mallinckrodt
16 obtained 867 data in connection with non-opioid
17 products it manufactured and sold?

18 MR. TSAI: Objection to scope. Go ahead.

19 A. Mallinckrodt did obtain 867 data for all
20 of our generic products, including non-opioids, yes.

21 Q. (By Mr. Ko) Got it. Thank you. And was
22 there ever a time that you recall that Mallinckrodt did
23 not obtain this 867 data for its generic products?

24 A. I do not recall exactly when we started

1 receiving 867 data from specific customers.

2 Q. Do you know whether or not the FDA ever
3 mandated or required Mallinckrodt to obtain such data,
4 such data being 867 data?

5 A. I am personally not aware of FDA
6 requirements for 867 data and I haven't had a chance to
7 read this e-mail chain in full.

8 Q. Do you have any understanding of -- so EDI
9 we discussed before was a data aggregator of lots of
10 things. Does the term 844 data ring a bell to you at
11 all?

12 A. Yes, I am generally familiar with what EDI
13 844 is.

14 Q. And what's your general understanding of
15 that?

16 A. That 844 data provides an additional level
17 of detail around our products -- the sales of our
18 products from distributors to their end customers.
19 Beyond that I'm not familiar with exactly what it
20 includes.

21 Q. And do you know whether or not
22 Mallinckrodt had acquire -- ever acquired 844 data with
23 respect to its generic products?

24 MR. TSAI: Objection to scope. Go ahead.

1 A. I believe that over the years we did
2 acquire some 844 data at some points in time.

3 Q. (By Mr. Ko) And similar to the 852 and
4 867 data, was the 844 data acquired via a distributor
5 or was it acquired via some other channel?

6 MR. TSAI: Objection to scope. Go ahead.

7 A. 844 data would have been supplied to
8 Mallinckrodt from our distributor customers.

9 Q. (By Mr. Ko) And do you know whether or
10 not either Cardinal, McKesson, or ABC had provi -- ABC
11 being AmerisourceBergen --

12 A. Uh-huh.

13 Q. -- had provided 844 data to Mallinckrodt
14 at any time with respect to Mallinckrodt's generic
15 products?

16 MR. TSAI: Objection to scope. Topic 11
17 does not include the subject of 844 data, but go ahead.

18 A. 844 data, as I mentioned, I'm not
19 completely familiar with when we acquired it, from
20 whom, or how we used those data, other than being aware
21 that we have acquired it from some distributors at some
22 point.

23 Q. (By Mr. Ko) You can put that aside. Does
24 the -- I know earlier you had talked about some

1 databases that had housed certain information, and I
2 believe you had referred to Cognos?

3 A. Cognos is the data query tool that we use
4 for our data warehouse.

5 Q. And approximately how long did -- or how
6 long has Mallinckrodt utilized Cognos as its data query
7 tool for its data warehouse?

8 A. For a very long time. I don't know
9 specifically when we started, but it was early 2000s.

10 Q. And is it fair to say that among the data
11 it warehouses, includes sales data?

12 A. Yes, sales data is included in our data
13 warehouse, yes.

14 Q. And what about Essbase? E-S-S-B-A-S-E.
15 Does that database sound familiar to you at all?

16 A. Yes, I am generally familiar with what it
17 is.

18 Q. And what is your understanding of what it
19 is?

20 A. Essbase I believe was our financial system
21 or financial query tool which was used to -- by the
22 finance team to generate reports or analysis of
23 financial data.

24 Q. And did you ever utilize Essbase in

1 connection with any financial plans or documents you
2 were involved in connection with your marketing roles
3 at Mallinckrodt?

4 A. I did not personally utilize Essbase, but
5 I would have received reports that were created by the
6 finance team using Essbase.

7 Q. What about DART? D-A-R-T. Does that
8 database sound familiar to you at all?

9 A. Yes.

10 Q. And how did Mallinckrodt, if at all,
11 utilize that database?

12 A. DART is our database for capturing and
13 paying invoices for purchases made in the normal course
14 of business such as office supplies, professional
15 services agreements. Anything not production-related.

16 Q. Got it. Got it. And earlier we talked
17 about the J.D. Edwards database. Do you recall that?

18 A. Yes.

19 Q. Is there a -- I've seen references in
20 documents to JDE and JDA. Is there a -- are those both
21 in reference to J.D. Edwards, or are those two
22 different things, if you know?

23 A. JDE is the short form for J.D. Edwards.
24 JDA is a completely different system which is used for

1 forecasting and planning production.

2 Q. Forecasting and planning production of
3 what?

4 A. Manufacturing of our products.

5 Q. Including --

6 A. All of our generic products.

7 Q. What about with respect to branded
8 products? Any coverage there?

9 A. Yes, I believe JDA was used for
10 forecasting and planning of production of our branded
11 products or of ordering production from contract
12 manufacturing organizations.

13 Q. And what about -- I'm sure you'll know
14 this -- IMS? Mallinckrodt utilized IMS data with
15 respect to its -- the products it manufactured;
16 correct?

17 A. Yes, Mallinckrodt utilized IMS data for
18 all of our products as well as full market analysis.

19 Q. And I know that there have been various
20 iterations, if you will, of IMS and there's various
21 entities that are involved. Can you describe for me
22 what entities Mallinckrodt purchased IMS or IMS-type
23 data from from the period in which -- from between the
24 period in which it first manufactured an opioid product

1 to present?

2 A. So I don't recall all of the names that
3 these entities used to have, but the primary names were
4 IMS Health and Wolters Kluwer and the predecessor
5 entities to Wolters Kluwer -- the database that they
6 provided.

7 Q. Does the entity or database Xponent sound
8 familiar to you?

9 A. Xponent is a database, if you will, that
10 is provided by IMS Health.

11 Q. And so in connection with Mallinckrodt's
12 acquisition of IMS data it also acquired Xponent data;
13 is that fair to say?

14 A. Mallinckrodt did acquire Xponent data in
15 support of our branded products.

16 Q. So only in support of the branded
17 products?

18 A. That's correct.

19 Q. And the database ValueTrak. Does that
20 ring a bell to you?

21 A. Yes. ValueTrak is the database provided
22 by ValueCentric, and that is the third-party EDI data
23 aggregator that we currently use.

24 Q. So that -- so earlier we looked at

1 IntegriChain as making a proposal to house data,
2 including EDI data, but as far as your knowledge,
3 Mallinckrodt never retained IntegriChain but instead
4 has retained ValueTrak to aggregate data, including EDI
5 data; correct?

6 A. We have never to my knowledge retained
7 IntegriChain for those purposes. The only third-party
8 aggregator I'm aware of is ValueCentric, who's
9 aggregated EDI data for us.

10 Q. And that EDI data includes 852 and 867
11 data; correct?

12 A. That is correct.

13 Q. Now, we were talking a moment ago about
14 IMS data. What's your general understanding of --
15 strike that. What time period did Mallinckrodt to the
16 best of your knowledge acquire IMS data?

17 A. To the best of my knowledge we began
18 acquiring IMS data around the year 2000 with historical
19 data starting in about 1998.

20 Q. And it continues to purchase this data in
21 some form today; correct?

22 A. Yes --

23 Q. Mallinckrodt -- and it being Mallinckrodt?

24 A. Right, Mallinckrodt continues to purchase

1 data from what is now IQVIA.

2 Q. And can you describe to the court why
3 Mallinckrodt purchased IMS/IQVIA data in connection
4 with its -- in connection with this portfolio?

5 A. Mallinckrodt purchased IMS or IQVIA data
6 for a number of different purposes. Relative to our
7 generic portfolio, we purchased those data in order to
8 understand the overall size of markets for individual
9 products, to try to understand trends in those markets
10 and understand market share between either products or
11 competitors on individual generic products. We used
12 that in support of both our currently -- then-current
13 commercialized products as well as evaluation of new
14 product opportunities.

15 Q. So is it fair to say that Mallinckrodt
16 purchased IMS/IQVIA data in connection with both its
17 branded and generic opioid products?

18 A. Mallinckrodt did purchase IMS or IQVIA
19 data for both brands and generics, yes.

20 Q. And do you have any understanding of how
21 much Mallinckrodt paid to acquire this data on an
22 annual basis?

23 A. I have a general understanding at
24 different points in time but don't have a comprehensive

1 understanding in total.

2 Q. Sure. And what's your general
3 understanding?

4 A. In the early 2000s, early to mid-2000s, we
5 spent something on the order of \$100,000 or \$200,000 a
6 year. During the time period when we had Xponent data,
7 I know the IMS contract was in the low single-digit
8 millions per year, and today we spend -- I believe it's
9 a little bit over \$300,000 per year for domestic IMS
10 data, which is used on a corporate-wide license for
11 products outside of SpecGX as well.

12 Q. Okay. I'm sorry to interrupt. And do --
13 so it sounds like you also then pay for and receive
14 some international IMS data?

15 A. We do as a company pay for and receive
16 XUS, international IMS data, yes.

17 Q. And when did Mallinckrodt start paying for
18 international data?

19 MR. TSAI: Object to the scope.

20 A. I'm not sure exactly when we started. We
21 have had access sporadically over the years to
22 international data.

23 Q. (By Mr. Ko) And who -- which department
24 was in charge of acquiring IMS data?

1 A. Originally, when we first started
2 acquiring data, the generics product management team
3 was acquiring that data. In the 2007-2008 time frame
4 we formed a corporate strategy and portfolio team which
5 included a market research group and the responsibility
6 for data transferred to that group at the time. Since
7 about 2016, that group was dissolved and now the
8 corporate IT team is responsible for data purchases.

9 Q. And going back to when you were talking
10 about the generics product management team acquiring
11 this data, once they acquired it, who was it generally
12 disseminated to? In other words, what teams at
13 Mallinckrodt would receive IMS data?

14 A. Over time -- I can't speak to everyone --
15 but the primary groups would have been the product
16 management and marketing team, the national accounts
17 team, and business development.

18 Q. And by the way, on the marketing team, did
19 Mallinckrodt distinguish marketing team between its
20 brand products and its generic products, or was there
21 just one marketing team that led both aspects of
22 Mallinckrodt's business?

23 A. Mallinckrodt had separate product
24 management and marketing teams for all of our different

1 product categories over time, so generics and branded
2 teams were separate. At various points in time we did
3 have a centralized marketing services team which
4 supported those groups, but the actual marketing and
5 product management functions were separate.

6 Q. And the IMS data was shared within both
7 the generics and branded teams; is that correct?

8 A. Some of the IMS data was shared.
9 National-level data was shared between the teams.
10 Xponent data was not shared. It was held within and
11 used by only the brand team.

12 Q. So the Xponent was not shared or was not
13 disseminated beyond the brand team at all, or just not
14 shared with the generic aspect of the business?

15 A. So the Xponent data was not shared with
16 the generic team. The Xponent data would have been
17 used to compile reports on the business or other types
18 of metrics which would have been reported up to
19 management.

20 Q. Did the IMS data allow Mallinckrodt to
21 track number of contacts to physicians?

22 A. No, IMS data does not track contact with
23 physicians.

24 Q. Do you mean in the sense that -- well,

1 let's take a step back. Do you know whether or not IMS
2 had the capability of tracking the number of contacts
3 to physicians?

4 MR. TSAI: Object to scope. Object to
5 form. Excuse me. Go ahead.

6 A. I am not aware if IMS had that capability.

7 Q. (By Mr. Ko) So as far as your
8 understanding is, Mallinckrodt did not purchase IMS
9 data to gain insight into the number of contacts sales
10 reps may have had with doctors?

11 A. No, I am not aware of us purchasing that
12 data.

13 Q. Do you know in connection with the IMS
14 data that Mallinckrodt purchased whether or not the
15 data could be aggregated by specialty in terms of
16 physician specialty and their prescribing habits?

17 A. The IMS data which we purchased at both a
18 detailed level in Xponent and at a national level --
19 the prescription dispense data does have prescriber
20 specialty associated with that information.

21 Q. And does the IMS data also allow
22 Mallinckrodt to track dosage?

23 A. Can you elaborate on what you mean by --

24 Q. Sure. Have you heard of the term MME?

1 A. Yes, I have.

2 Q. And does -- and so the record is clear,
3 what's your understanding of what MME is?

4 A. MME is morphine milligram equivalence.
5 I've also seen milligram morphine equivalence. It is a
6 way to adjust the milligram strength or the strength of
7 a given opioid into a common morphine equivalent
8 number.

9 Q. And do you have any understanding of
10 whether or not Mallinckrodt acquired IMS data to track
11 and understand MME amounts of its products and its
12 competitors' products?

13 A. Mallinckrodt did not acquire IMS data for
14 the purposes of tracking MMEs for either our products
15 or competitors.

16 Q. Do you know whether or not any of the data
17 that IMS purchased contained MME amounts or -- yeah.

18 MR. TSAI: Objection to form.

19 Q. (By Mr. Ko) Strike that. Do you know
20 whether or not the data that Mallinckrodt purchased
21 from IMS contained MME amounts?

22 A. The data we purchased from IMS did not
23 contain MME data.

24 Q. Did IMS -- currently IQVIA -- data allow

1 Mallinckrodt to track total sales of its products and
2 its competitors' products?

3 A. IMS data allow Mallinckrodt to view an
4 estimated total sales volume in terms of units of our
5 products as well as our competitors' products at a full
6 market U.S. market level.

7 Q. And how are you defining total sales
8 volume?

9 A. So it depends on the time period you look
10 at, but a given product, IMS data would show the total
11 quantity sold based upon the IMS projection of what the
12 total market is, and they provide that data broken down
13 by manufacturer, by product, and by selling channel or
14 class of trade.

15 Q. And when you said total quantity, what do
16 you mean by that? How are you defining quantity?
17 Pills or MMEs, or how?

18 A. So IMS provides a few different measures.
19 They track selling units, they track individual dosage
20 units, and they also provide the milligram strength for
21 each of those dosage units, and from that milligram
22 strength and total dosage units, they calculate a total
23 kilograms of active ingredient.

24 Q. So just so I understand, you're defining

1 total quantity to include the milligram strength by --
2 excuse me. I just want to unpack kind of your answer
3 here --

4 A. Uh-huh.

5 Q. -- because there's a lot of things that
6 went into it.

7 A. Yeah.

8 Q. So in terms of total quantity and what you
9 were purchasing from IMS, it included, among other
10 things, a total kilograms of active ingredient; is that
11 correct?

12 A. One of the -- excuse me. One of the data
13 elements that IMS provides in the dataset that we
14 purchase is a total-kilogram metric which they
15 calculate from the milligram strength of the given
16 product and the total quantity reported as sold for
17 that product, and it's a straight multiplication.

18 Q. That's helpful. And in addition to that,
19 you had also purchased from IMS individual dosage
20 units; correct?

21 A. Our data feeds included both at the
22 package and dosage-unit level.

23 Q. And have you ever heard of the term
24 extended unit?

1 A. Yes.

2 Q. What's your understanding of extended
3 unit?

4 A. Extended unit is the smallest measurable
5 unit in a given package for sale. So most often for a
6 tablet product, an individual tablet is an extended
7 unit. For a liquid product it might be a milliliter,
8 if that's how the product is packaged in terms of a
9 milliliter quantity -- the smallest packaging unit.

10 Q. And --

11 A. Unit packaged. I'm sorry.

12 Q. And so in other words, would it be a fair
13 characterization that extended unit represents the
14 vehicle in which the opioid is delivered? Like you
15 said, it could be either in a tablet or it could be in
16 liquid form or some other form?

17 A. I would term it the individual dosage
18 unit.

19 Q. Rather than extended unit?

20 A. Let me clarify. Extended unit means the
21 individual dosage unit of a given product.

22 Q. And the individual dosage unit -- strike
23 that. What -- how is the milligram amount factored
24 into an individual dosage unit?

1 A. So in general terms, pharmaceutical
2 products are formulated to contain a certain amount of
3 active ingredient, and that amount is part of the
4 labeled dosage per unit, and that specific dosage is
5 captured in the data feed that we purchase from IMS.

6 Q. I'm going to hand you a copy of what will
7 be marked as KV Exhibit 7.

8 [Exhibit Mallinckrodt-Vorderstrasse-007
9 marked for identification.]

10 MR. TSAI: David, we've been going an hour
11 since the last break. After this exhibit, can we take
12 another 10-minute break?

13 MR. KO: Is it possible -- I don't know
14 the status on lunch, but is it possible to go up to
15 lunch?

16 THE VIDEOGRAPHER: Yeah, we need to place
17 the order, though.

18 MR. KO: Oh, we haven't placed the order.
19 Okay. Well, that probably warrants a break.

20 MR. TSAI: Okay.

21 MR. KO: Sure, why don't we do it after
22 this document?

23 Q. (By Mr. Ko) So you've been handed a copy
24 of KV Exhibit 7 by the court reporter, and this exhibit

1 I'll note for the record contains a cover e-mail and
2 attachment, and the cover e-mail is Bates-stamped
3 MNK-T1_0000754547. And unless you need to refer to the
4 cover e-mail -- I mean, you're more than welcome to,
5 but I have mostly questions about this attachment that
6 is titled U.S. pain market update dated October 16th,
7 2012. Does this document look familiar at all to you?

8 A. This specific document does not look
9 familiar. I recognize the general format and the data
10 that it appears to present.

11 Q. And what type of data is it presenting?

12 A. It is presenting an historical analysis of
13 IMS data. Appears to be data that has been summarized
14 or analyzed in some way and presented at a market
15 segment level.

16 Q. And when you said earlier that you
17 recognized the general format, what did you mean by
18 that?

19 A. Meaning that the specific terms that are
20 included in various different points referring to data,
21 I know what those terms mean and understand -- from
22 what I've been able to read about some of the
23 commentary in here, I understand what is being talked
24 about.

1 Q. And if you comb through this document
2 starting with the first page, Page 2 --

3 A. Uh-huh.

4 Q. -- you'll see some graphs, and they
5 reveal some source material. You see that on the
6 bottom right-hand corner?

7 A. Yes.

8 Q. And the source material includes IMS NSP
9 and NPA --

10 A. Uh-huh.

11 Q. -- October 2006 through July 2012. Did I
12 read that correctly?

13 A. Yes, you did.

14 Q. So we talked about IMS. What is your
15 understanding of NSP data?

16 A. NSP stands for national sales
17 perspectives. That is the dataset that IMS provides
18 which reports sales of pharmaceutical products to
19 pharmacies at a national level. It provides product
20 aggregated at the most granular level at the selling
21 channel or class of trade.

22 Q. And so it's data that is produced in
23 connection with Mallinckrodt's purchase of IMS data; is
24 that fair?

1 A. It is purchased as part of our IMS data
2 purchase, yes.

3 Q. And what about with respect to NPA? What
4 does NPA stand for?

5 A. NPA is national prescription audit.
6 National prescription audit is the IMS database which
7 provides a full U.S. market projection of product and
8 prescriptions dispensed from pharmacies to patients.
9 Again, it is product specific, but the most granular
10 level is at a selling channel level, and that
11 information does include specialty.

12 Q. And by specialty, you mean by physician
13 specialty?

14 A. Correct. Prescriber specialty is captured
15 for the prescription dispense data.

16 Q. And so similar to the NSP information,
17 Mallinckrodt acquired the NPA data in connection with
18 its purchases of IMS data; is that correct?

19 A. That is correct.

20 Q. And by the way, on this page, it's titled
21 U.S. pain market is flattening. You have on the bottom
22 left-hand column some general commentary with respect
23 to the pain market. Do you see that?

24 A. I do.

1 Q. And again, going back to the beginning of
2 this document, it is dated October 16th, 2012, and so
3 this appears to be a reflection of Mallinckrodt's
4 perspective on the pain market at the time. Is that
5 fair to say?

6 A. This appears to be our aggregation of the
7 pain market as we defined it at that time, yes.

8 Q. And then it indicates in the -- there are
9 two major bullets, but in the first bullet underneath
10 the second bullet there is a phrase there that
11 indicates that scrutiny of opioid prescribing is
12 increasing. Do you see that?

13 A. I do.

14 Q. Do you have an understanding of what that
15 is referring to?

16 A. I have a general understanding of what it
17 is referring to.

18 Q. And what's your general understanding?

19 A. That would refer to the -- during this
20 period of time when this report was generated that the
21 prescribing of opioids was being reevaluated from many
22 different sides to understand if the prescribing met
23 all of the expectations of everyone involved.

24 Q. And when you say many different sides --

1 A. Yeah.

2 Q. -- what do you mean by that?

3 MR. TSAI: Objection to scope.

4 A. My understanding during this period of
5 time, medical professionals, prescribers, medical
6 professional societies, FDA, others, were actively
7 looking at the use of opioids in the U.S. and trying to
8 form opinions about that use.

9 Q. (By Mr. Ko) And would it be fair to say
10 that this scrutiny also is increasing as a result of
11 abuse, diversion, and misuse of prescription opioids?

12 MR. TSAI: Objection to scope.

13 A. So the scrutiny for -- of opioids in the
14 U.S. has been a result of many factors over time. I
15 can't speculate exactly what this comment is referring
16 to or exactly what was driving all of that scrutiny in
17 the marketplace.

18 Q. (By Mr. Ko) Sure. But is it fair to say
19 that Mallinckrodt was aware that there was some
20 scrutiny with respect to opioid prescribing at least as
21 of October 16th, 2012, and according to this document;
22 correct?

23 A. It's fair to say that according to this
24 document we were aware at this -- at the time of this

1 document of scrutiny of opioid prescribing.

2 Q. And would it be fair to say that scrutiny
3 includes the abuse, misuse, and diversion of
4 prescription opioids?

5 MR. TSAI: Objection to scope.

6 A. I can't say whether it would be fair to
7 say if scrutiny includes that, since I don't know the
8 details behind this comment.

9 Q. (By Mr. Ko) Putting aside this document,
10 the -- was Mallinckrodt ever concerned when it was
11 manufacturing its opioids regarding the abuse potential
12 and the misuse potential of its products?

13 A. The abuse or misuse potential of opioids
14 is a very commonly understood fact about these
15 products. They have a risk and they have a benefit.
16 The FDA and other professional groups do what they can
17 to ensure that prescribers are educated about those
18 risks. We as a company do our part to make sure that
19 we communicate those risks when we get the chance to,
20 and we have understood for a long time our
21 responsibility as a provider of opioid products.

22 Q. And when you say the abuse or misuse
23 potential of opioids is very commonly understood, would
24 you say that that was commonly understood by

1 Mallinckrodt since the beginning of when it first
2 started manufacturing prescription opioids?

3 A. To the best of my knowledge, even from the
4 time when we first manufactured prescription opioids,
5 those opioids were labeled with warnings around their
6 risks and it was understood that these products could
7 be abused.

8 Q. And what about -- I understand your
9 reference to the labels, but the question was
10 specifically about the abuse and misuse potential of
11 opioid products. Did Mallinckrodt understand when it
12 first started manufacturing opioid products in the
13 mid-1990s of their abuse and misuse potential?

14 A. Mallinckrodt understood that abuse and
15 misuse of opioids was possible and that it occurred. I
16 don't believe we had any specific data about the
17 specific potential of any of our individual products.

18 Q. And when you say you don't have any
19 specific data, do you mean at that time or throughout
20 the time that Mallinckrodt manufactured opioid
21 products?

22 A. I believe that at that time and throughout
23 the time that we manufactured opioid products, we did
24 not generate any data to draw conclusions on the

1 specific abusability of any of our products.

2 Q. And setting aside abuse and misuse, does
3 the concept or term diversion mean anything to you?

4 MR. TSAI: Objection to scope.

5 A. Yes, I am aware of the concept and the
6 term.

7 Q. (By Mr. Ko) What's your understanding of
8 diversion?

9 MR. TSAI: Can I get a standing objection
10 on this line of questions about diversion as to scope?

11 MR. KO: Sure. And I'll respond to that
12 scope objection by referring you to -- sorry, Kevin.
13 Bear with us. I'll respond to that standing objection
14 by reference to Topic 29, which Mallinckrodt designated
15 Kevin to testify on, which discusses among other things
16 Mallinckrodt's knowledge regarding the abuse, misuse,
17 and dependence of its opioid products.

18 MR. TSAI: Which does not use the term
19 diversion, and diversion is a specific term used in
20 other topics for which you'll get an opportunity to ask
21 questions of our -- another designee. But go ahead.

22 A. My understanding of diversion is a term
23 that refers to the movement of opioid products into the
24 hands of people or into a location other than where

1 that product was intended to go.

2 Q. (By Mr. Ko) And do you know whether or
3 not Mallinckrodt investigated or generate -- strike
4 that. Did Mallinckrodt ever investigate the diversion
5 potential of its opioid products at any time?

6 A. I am not aware that we ever investigated
7 the diversion potential of our products.

8 MR. KO: We can take a break.

9 THE VIDEOGRAPHER: We are going off the
10 record at 11:51 AM.

11 [A brief recess was taken.]

12 THE VIDEOGRAPHER: We are back on the
13 record at 12:38 PM.

14 Q. (By Mr. Ko) Welcome back from lunch,
15 Kevin. I want to turn your attention back to Exhibit
16 2.

17 A. Okay.

18 Q. Gave you Exhibit 2. And on Page 3, at the
19 bottom of Page 3, there's a reference to Topic 19. Do
20 you see that?

21 A. Yes.

22 Q. And in connection with Topic 19, it
23 appears that you -- in addition to reviewing documents,
24 you received information from Kathy Schaefer, George

1 Kegler, and Jeff Kilper. Do you see that?

2 A. Yes.

3 Q. And as you alluded to earlier, this -- you
4 didn't actually speak with them, but you received
5 documents from them -- correct -- as selected by
6 counsel?

7 A. As selected by counsel. Received finance
8 documents for review, which were compiled or put
9 together in part by them.

10 Q. And who is Kathy Schaefer?

11 A. Kathy Schaefer is -- I guess she's our
12 treasurer now.

13 Q. And treasurer of both the LLC --
14 Mallinckrodt LLC and SpecGX, or one over the other?

15 A. I believe she's treasurer of the LLC.

16 Q. And how about George Kegler? Who is he?

17 A. George Kegler was the vice-president of
18 finance for SpecGX.

19 Q. And Jeff Kilper -- who is he?

20 A. Jeff Kilper was or is senior director of
21 finance for SpecGX.

22 Q. So I know we touched on this before, but
23 just so the record is clear, Mallinckrodt did in fact
24 maintain financial information and accounting

1 information regarding marketing expenditures with
2 respect to its opioids that it manufactured; correct?

3 A. We captured our marketing expenditures as
4 part of our general profit-and-loss documents for the
5 business. For the branded products we generally
6 maintained a product-specific P & L where we would
7 allocate marketing costs specifically to products. For
8 the generics business we did not allocate marketing
9 costs to specific products and captured those at a
10 whole department level.

11 Q. And by whole department level, you had a P
12 & L for the entire generic line of business, in other
13 words; correct?

14 A. That is correct. Yes.

15 Q. And with respect to -- actually, scratch
16 that, or strike that. In addition to P & L statements,
17 were there any other types of financial statements that
18 Mallinckrodt possessed or maintained that tracked its
19 opioid products?

20 A. From time to time in the generics
21 business, we would generate periodic sales reports
22 which were used to assess progress towards budget or
23 forecast, and that would cover all of our products in
24 the portfolio. I am not familiar with the specific

1 format for similar reports on the branded side of the
2 business, but I'm aware that similar reports were used.

3 Q. And when you say that they're periodic, do
4 you have any idea or understanding of how frequent they
5 were?

6 A. It has varied over time. Weekly or
7 semiweekly, on occasion, monthly reports or even
8 quarterly business review reports.

9 Q. And with respect to both the brand and
10 generic portfolio of Mallinckrodt, what department was
11 in charge of tracking this financial information?

12 A. The finance department tracked it.

13 Q. And were -- did the marketing department
14 ever have any involvement in preparing the financial
15 information we were discussing?

16 A. The marketing department for the branded
17 side would have been involved in analysis of the
18 financial information relative to their plans or
19 targets for the year. The product management team on
20 the generics side would have done the same -- analyzed
21 financial data relative to progress against targets.

22 Q. The court reporter is going to hand you a
23 copy of what's been marked as KV Exhibit 8.

24 [Exhibit Mallinckrodt-Vorderstrasse-008

1 marked for identification.]

2 Q. Now, for the record, the court reporter
3 has handed you a copy of KV Exhibit 8, which is
4 Bates-stamped MNK-T1_0000432950, an e-mail chain from
5 October 15th, 2010, that contains an attachment, which
6 is at MNK-T1_0000432952. So it appears that this
7 e-mail chain involves some financial statements
8 involving the generic aspect of Mallinckrodt's business
9 and involves among other people Randy Meisner. Do you
10 know who Randy Meisner is?

11 A. Yes, I do.

12 Q. And who is he?

13 A. Randy Meisner at this time was the
14 controller for the generics business.

15 Q. And was he generally responsible for
16 creating financial statements including forecasts of
17 the generic side of the business?

18 A. He was responsible for generating reports
19 on the financial state of the business and for
20 compiling and generating the financial forecast.

21 Q. And did he have any responsibility with
22 respect to the branded aspect of Mallinckrodt's
23 business?

24 A. Not to my knowledge.

1 Q. And so he's attaching, as you can see,
2 some financial statements which I referred to earlier,
3 and the attachment appears to be some P & L statements
4 regarding the specialty generics line of Mallinckrodt's
5 business. Is that correct?

6 A. Yes, that's correct.

7 Q. And earlier we had talked about
8 Mallinckrodt's gross sales with respect to its generic
9 line of business, and we have that captured here at
10 least in terms of actual numbers for fiscal year 2010
11 and some budget and expected numbers for 2011. Is that
12 accurate?

13 A. Yes, that appears accurate.

14 Q. And can you remind the court your
15 definition of gross sales -- how you determined or how
16 you defined gross sales as it relates to the generic
17 business of Mallinckrodt?

18 A. Conventionally we in the generics business
19 have defined a term which we call modified gross sales,
20 which is a reflection of the contract price for any
21 sales that occur on a direct basis and the wholesale
22 acquisition cost for sales that occur through
23 wholesalers. Any direct sales would be sales into a
24 warehouse or distribution center that's run by a

1 pharmacy chain.

2 Q. And is that definition captured in these
3 numbers here in terms of gross sales of specialty
4 generics?

5 A. I don't have enough information in this
6 document to say whether that exact definition was used
7 for this gross sales.

8 Q. Do you have any reason to doubt that this
9 is an annual profit-and-loss statement for the
10 specialty generics division, at least with respect to
11 actual fiscal year 2010 and forecasted numbers for
12 2011?

13 A. It appears correct to me, yes.

14 Q. And help me understand -- well, strike
15 that. Underneath gross sales we have some line items
16 for chargebacks. Do you see that?

17 A. Yes.

18 Q. And earlier we were talking about
19 substantial amounts Mallinckrodt was providing to
20 distributors for chargebacks.

21 A. Uh-huh.

22 Q. Do you see these numbers here on the
23 chargeback line item?

24 A. Yes.

1 Q. And so these are the amounts that
2 Mallinckrodt is paying to distributors pursuant to
3 those agreements that we had discussed earlier this
4 morning; is that correct?

5 A. Yes, those are chargeback amounts pursuant
6 to the chargeback agreements.

7 Q. So in 2010 the actual amount spent by
8 Mallinckrodt in terms of chargebacks paid to
9 distributors was approximately \$700 million; is that
10 correct?

11 A. Yes, that's correct.

12 Q. And Mallinckrodt budgeted approximately
13 that same amount -- a little less, but approximately
14 \$686 million for 2011; correct?

15 A. Yes, that was the working budget.

16 Q. And just so the record is clear, can
17 you -- or what is OCT LE? Is that October --

18 A. October, latest estimate.

19 Q. And so for -- in other words, what that's
20 capturing is as of October that was the latest estimate
21 for the projection of that year, what the amount would
22 be?

23 A. Correct.

24 Q. And so for this two-year time period it

1 appears that Mallinckrodt has both paid and is
2 expecting to pay anywhere from \$660 to \$700 million in
3 chargebacks to distributors; is that correct?

4 A. Yes, that's correct.

5 Q. And do you know before and after this time
6 whether or not that same -- that number was generally
7 the same? Did it fluctuate significantly or was it
8 around the \$650 to \$700 million range?

9 A. So I don't know if it was around the same
10 range, but as a proportion of gross sales it was likely
11 to be relatively consistent.

12 Q. And thank you for that. So as a
13 proportion of gross sales here we have -- at least in
14 actual 2010 numbers it was an amount that was over 50
15 percent. I think if I do the math it's almost --

16 A. Uh-huh.

17 Q. -- it's like 50 -- approximately 57
18 percent of all the gross sales is represented in
19 chargebacks. Is that correct?

20 A. Yes, that appears to be correct.

21 Q. And so that number that appears below the
22 gross sales number -- the gross less chargebacks --
23 without sounding too obvious, that is basically the
24 \$1.3 million minus the 700K -- or \$700 million in

1 chargebacks?

2 A. Yes, that's correct math.

3 Q. And so when you said earlier that the
4 relative proportion of chargebacks to sales remained
5 pretty constant over time, do you mean to say that --
6 or is one way of saying that that chargebacks
7 represented approximately 50 to 60 percent of
8 Mallinckrodt's gross sales on specialty generics
9 throughout the relevant time period?

10 A. It's my general understanding that
11 chargebacks have -- for generic products over the
12 relevant time frame have generally been somewhere in
13 the neighborhood of about half -- excuse me -- half of
14 the total gross sales.

15 Q. That's helpful. And below the line item
16 chargebacks you see that row rebates?

17 A. Uh-huh. Correct.

18 Q. And we had discussed before the concept of
19 rebates, and so again, these are amounts Mallinckrodt
20 is paying to distributors in the form of rebates and/or
21 discounts as payment pursuant to the agreements
22 Mallinckrodt had with distributors; correct?

23 A. Yes, all of these would be governed by
24 agreements with distributors.

1 Q. And just so we're clear -- and I want to
2 make sure because we talked about both distributors and
3 pharmacies earlier this morning -- on this line item,
4 these rebates -- are they also solely with respect
5 to -- are these amounts only being paid to distributors
6 or do these amounts reflect any amounts paid to
7 pharmacies as well?

8 A. From this document I don't have the detail
9 to completely answer the question, but I would
10 interpret this to include rebates paid to wholesalers
11 and distributors as well as some rebates that were paid
12 to pharmacy chains.

13 Q. And same question with respect to
14 chargebacks. I know we had -- you had testified
15 earlier this morning that the chargeback amounts were
16 only provided to distributors, but to the extent that
17 there were also chargebacks provided to pharmacies,
18 does this amount presumably cover amounts paid to both
19 types of entities?

20 A. So the -- excuse me. The generic cost
21 differential that we discussed earlier relative to Rite
22 Aid -- I don't know where this would be captured in
23 these data just based upon what's outlined here.

24 Q. By the way, the generic cost differential

1 issue that we talked about earlier this morning that
2 existed between Mallinckrodt and Rite Aid -- did
3 looking at that contract earlier this morning refresh
4 your recollection at all as to other similar types of
5 agreements that Mallinckrodt had with other pharmacies
6 that were similar to the one we discussed?

7 A. In general terms, we over the years in the
8 generics business have from time to time with chain
9 pharmacy customers offered what we term a wholesaler
10 differential. That is the difference between the
11 acquisition price that we list for a customer for a
12 pharmacy chain at the distributor, so the price that
13 they can purchase the product for from the
14 distributor -- the difference between that price and
15 our agreed-upon contracted price that would apply to
16 direct sales to that chain pharmacy customer.

17 So if a chain pharmacy customer was unable
18 for whatever reason to purchase a product directly into
19 their warehouse and they had to go to a wholesaler to
20 purchase that product, that -- if that product was sold
21 to them at a higher price, the difference between that
22 higher price and the negotiated direct selling price we
23 would reimburse them for as a wholesaler differential.

24 Q. That's helpful. Turning further down that

1 page, there are some line items that discuss the
2 marketing budget of specialty generics. Do you see
3 that row that I'm highlighting here?

4 A. Yes.

5 Q. So it appears that relative to the overall
6 expenses, the -- marketing was lower, but there's some
7 marketing of specialty generics going on; is that fair
8 to say?

9 A. We did conduct some marketing activities
10 for specialty generics in the form of attendance at
11 trade shows, providing selling materials to the sales
12 team to help them in communicating our product line to
13 the wholesalers and chain pharmacies, as well as some
14 product availability advertising that we would have
15 placed in trade publications.

16 Q. So that's very helpful. So the conduct
17 that you just described there -- those expenses are
18 captured in these numbers here? Is that accurate?

19 A. Those expenses are captured in addition to
20 the personnel expenses for anyone who was in product
21 management or marketing or market analytics functions.

22 Q. And so just so the record is clear,
23 Mallinckrodt did engage in marketing of its specialty
24 generic products; is that correct?

1 A. Defining marketing as providing product
2 information around availability of products and
3 providing the sales team with documents necessary to
4 communicate about our products with our wholesale
5 customers, yes, we did engage in those types of
6 marketing activities.

7 Q. And yes, you did engage in those types of
8 marketing activities with respect to your generic line
9 of business; is that correct?

10 A. Yes, we engaged in those activities
11 relative to the marketing of our generic business.

12 Q. Now, earlier this morning you had
13 testified about how Mallinckrodt had derived
14 substantial revenue from its generic portfolio. Do you
15 recall that?

16 A. Yes, I recall that.

17 Q. And in particular I think you had said
18 that a fair amount of revenue was obtained by
19 Mallinckrodt through its sale of oxy 15s and oxy 30s.
20 Is that accurate?

21 A. At different points in the past, oxycodone
22 15 milligram and 30 milligram have been at times a
23 small portion of our sales and at some times a slightly
24 larger portion.

1 Q. And when they were a slightly larger
2 portion, that was approximately from the 2005 to 2010
3 time period; is that fair?

4 A. I -- excuse me. I would have to see the
5 detailed documents in order to understand if that's a
6 correct time period.

7 Q. Do you have any understanding of the
8 general time period in which the oxy 15s and oxy 30s
9 were a source of substantial revenue for the company?

10 A. I am not aware of a specific time period
11 where I would consider them a substantial source of
12 revenue.

13 Q. Is it fair to say that Mallinckrodt has a
14 large market share of generic opioid products at this
15 time?

16 A. At this time Mallinckrodt does have the
17 Number 1 market share of generic opioids in the U.S.

18 Q. (By Mr. Ko) And how long has
19 Mallinckrodt -- approximately how many years has
20 Mallinckrodt held the top spot in terms of generic
21 market share?

22 A. We have currently held the top spot in
23 market share for less than a year.

24 Q. And during the 2005 to 2012 time period,

1 can you describe or can you explain to the court what
2 position or what rank Mallinckrodt may have been in
3 terms of generic market share?

4 A. I don't have the specific numbers in front
5 of me, but I do know that during that time period we
6 were often Number 1 or Number 2 in the products that we
7 sold.

8 Q. And products being the generic products?

9 A. Generics products. Correct.

10 Q. And fast-forwarding back to present when
11 you said that Mallinckrodt currently has the Number 1
12 market share. Do you have a general understanding of
13 what percentage that represents relative to the overall
14 market share -- or overall market? Excuse me.

15 A. Of the products that we currently sell to
16 the market, of the opioid products, I believe our
17 market share is approximately 30 percent.

18 Q. And during the time period we were
19 discussing before when Mallinckrodt was either Number 1
20 or Number 2, what has been the general or approximate
21 percentage of Mallinckrodt's market share relative to
22 the rest of the market?

23 A. During the time period where we were
24 Number 1 or Number 2, often we were between 15 and 20

1 percent of the total market.

2 Q. And did -- with respect to the generics,
3 did Mallinckrodt further delineate or differentiate
4 between regions or territories in the United States?

5 A. We do not look at the generic business on
6 a regional or geographical level.

7 Q. Do you look at your branded market on a
8 regional or geographical level?

9 A. The branded products had a -- had
10 territories that was -- that were used by the selling
11 team to divide up resources and to set targets.

12 Q. Just a few more questions on this
13 document, or maybe just one set of further questions.
14 On -- going back to the top of the page, do you see the
15 line item allowances?

16 A. Yes.

17 Q. And it appears that that ranges from
18 anywhere from \$10 to \$13 million during the relevant
19 time period of this document. Can you describe to the
20 court what allowances are in the context of this
21 financial statement?

22 A. The -- my understanding of how allowances
23 are summarized here is that the majority of these costs
24 would be what we term shelf stock allowances. As

1 prices for our products decline, the inventory on hand
2 at the wholesalers -- it is revalued to a lower value
3 to match the new price, and that amount is credited to
4 them as a shelf stock allowance.

5 Q. I see. So it's -- strike that. Going
6 back to the cover e-mail and your testimony about Mr.
7 Meisner, he was again responsible for creating some of
8 these financial forecasts, and did I hear you correctly
9 that he sometimes would create these on a weekly basis?

10 A. So various different reports on the
11 business were created on a weekly basis. Of the
12 reports included in this attachment, I'm not aware that
13 any of those were calculated with that frequency.

14 Q. I see. And going back to the cover
15 e-mail, there are some other people that I'd just like
16 to ask you about real quickly. Who is Michael Gunning?

17 A. Michael Gunning was the vice-president and
18 general manager of the generics business at that time.

19 Q. And is he still with the company right
20 now?

21 A. No, he's not.

22 Q. And then Ginger Collier I understand to be
23 -- she was the director of the generics marketing
24 business; is that correct?

1 A. Yes, she was director of generics
2 marketing at that time.

3 Q. Do you know whether or not she had any
4 input or consulted with Randy in preparing the finances
5 or the financial forecasts?

6 A. I do not know if Ginger was involved in
7 any of these specific reports. She may have been
8 involved relative to asking for minor changes in
9 formatting or general presentation of the reports.

10 Q. And sorry to jump around, but going back
11 to the attachment, going back to the gross sales -- so
12 again here we have gross sales of the specialty
13 generics business amounting to approximately \$1.3
14 billion throughout these two years. How did that
15 compare to the gross sales of Mallinckrodt's branded
16 business?

17 A. During this time that number would have
18 been larger than the branded business gross sales.

19 Q. And can we talk about order of magnitude?
20 How much greater were gross sales in the specialty
21 generics business relative to the branded business of
22 Mallinckrodt?

23 A. I don't know the exact proportions.
24 The -- during this time period, the branded business

1 would have been probably 25 percent or less of the
2 sales of the combined two businesses -- branded and
3 generic.

4 Q. Was there ever a time during the period in
5 which Mallinckrodt manufactured opioid products in
6 which the gross sales of its branded products exceeded
7 25 percent of the gross sales of Mallinckrodt's generic
8 products?

9 A. I don't believe so.

10 Q. So in other words, throughout the time
11 period in which Mallinckrodt was manufacturing opioids,
12 it's fair to say that the generic line of business
13 represented a substantial portion of the overall sales
14 of its opioid products; is that correct?

15 A. So the sales of opioid products at -- it
16 depends on which number you're looking at. On a net
17 basis, the sales of opioid products from the generics
18 business have generally always exceeded the net sales
19 from the branded opioids, but I can't say for sure that
20 that was true in every year.

21 Q. Thank you for that clarification. So just
22 so I understand, you're saying that the net sales with
23 respect to Mallinckrodt's branded opioid products was
24 greater than the net sales of Mallinckrodt's generic

1 products?

2 MR. TSAI: I'll just object as to scope.
3 There's a specific topic about annual sales that the
4 parties have agreed will be answered in writing. But
5 go ahead.

6 A. So no, I believe generally the opposite,
7 that net sales of the -- our generic opioid products
8 were almost always greater than the net sales of our
9 branded opioid products, but I can't say for certain
10 that that was true in every year.

11 Q. (By Mr. Ko) Sure. Sorry. And I
12 misheard.

13 A. That's okay.

14 Q. So thank you for that clarification. I'm
15 going to hand you now a copy of what will be marked as
16 KV Exhibit 9.

17 [Exhibit Mallinckrodt-Vorderstrasse-009
18 marked for identification.]

19 Q. And so the record is clear, the KV Exhibit
20 9 represents an e-mail chain that starts at
21 MNK-T1_0000658227. And it took us until 1:00 this
22 afternoon, but I have an e-mail which actually has your
23 name on it.

24 A. Yeah, I noticed that.

1 Q. Do you see that? Do you recognize this
2 document at all?

3 A. I don't recognize this specific document,
4 but I do know what it is discussing in general.

5 Q. And what is it discussing in general?

6 A. This is discussing some impending changes
7 with the business with the Price Chopper grocery chain
8 and changes that they were making relative to their
9 chosen wholesaler source program.

10 Q. And it sounds like there's some additional
11 groups that are referenced in this e-mail, but
12 actually, before I get to that, it looks like Lisa
13 Cardetti is sending this to the marketing team. Do you
14 see that?

15 A. Yes.

16 Q. And you're a member of the marketing team?

17 A. Correct.

18 Q. And who is Lisa Cardetti?

19 A. Lisa Cardetti at this time was a national
20 account manager, I believe -- regional account
21 manager -- for the generics business. Part of the
22 national accounts team.

23 Q. And in the second paragraph -- I guess
24 it's the third paragraph -- excuse me -- of this

1 e-mail -- there's a reference to a cage/vault agreement
2 effective October 2012. Do you see that?

3 A. Yes.

4 Q. Can you describe to the court what types
5 of cage/vault agreements Mallinckrodt had with other
6 entities?

7 MR. TSAI: Objection as to scope. Topic
8 37G covers vault agreements, and that is another topic
9 that the parties have specifically agreed will be
10 responded to in writing rather than testimony. But go
11 ahead.

12 A. From time to time, customers -- pharmacy
13 chains -- in this case a food store chain with pharmacy
14 operations -- from time to time those customers have
15 explored the ability to purchase controlled substances
16 directly from the manufacturer as opposed to through a
17 wholesaler.

18 In order to do so, they would need to
19 invest in cage and vault structures in their
20 distribution centers, and because the cost to
21 distribute products from Mallinckrodt directly to a
22 retail chain's distribution center was lower than
23 distributing through wholesalers, it was financially
24 desirable for us to take on those types of selling

1 arrangements, and on occasion we did provide a type of
2 financial incentive or allowance which would help the
3 customer offset the cost of making this investment in
4 order to be able to purchase product directly to their
5 warehouse.

6 Q. And so the cage and vault structure is an
7 actual physical structure that we're referring to?

8 A. Yes, that's correct.

9 Q. And why was it important for Mallinckrodt
10 to incentivize a direct customer or subsidize the
11 purchase of a cage and vault?

12 MR. TSAI: Objection as to form and scope.
13 Go ahead.

14 A. When pharmacy chains purchase product
15 through a wholesaler, off of a wholesaler generic
16 source program, the wholesaler negotiates price and
17 rebates with the manufacturer such as Mallinckrodt and
18 then sets a price for that pharmacy chain.

19 When they negotiate these programs, the
20 combined rebate structure that Mallinckrodt provides
21 provides a very low net purchasing price to the
22 wholesaler, but they're able to then mark up the
23 product as far as the market will bear when selling to
24 the pharmacy chain. If we sell directly to the

1 pharmacy chain's warehouse, we are able to sell at a
2 higher net price than what we can sell through a
3 wholesaler generic source program, so it's a more
4 profitable contract for us.

5 Q. (By Mr. Ko) Do you have any understanding
6 of the amount of agreements that Mallinckrodt had
7 with -- for which Mallinckrodt would sell directly to
8 the pharmacy chain warehouse?

9 A. I don't know the specific numbers or
10 proportion of our contracts which were direct selling
11 contracts to pharmacy chains. I do know that that
12 proportion was greater in the past than it is today.

13 Q. And when we talk about proportion, can you
14 give the court a general understanding of the
15 approximate percentage relative to all of the
16 agreements Mallinckrodt had?

17 A. Relative to the number of agreements we
18 had, at its peak -- excuse me -- direct selling
19 contracts were probably 10 to 20 percent of our total
20 contracts and maybe as much as 30 or 40 percent of the
21 product volume that we sold.

22 Q. And the product volume including branded
23 and generics, or are we just talking generics right
24 now?

1 A. This is all specifically dealing with
2 generics.

3 Q. And did you have a cage and vault
4 provision in any of your agreements with pharmacy
5 chains directly with respect to branded products that
6 Mallinckrodt manufactured?

7 MR. TSAI: Objection to scope.

8 A. I am not aware of any branded cage
9 programs or vault programs.

10 Q. (By Mr. Ko) And with respect to the
11 physi -- the actual physical cage and vault structure,
12 was one of the reasons that Mallinckrodt -- strike
13 that. Was one of the reasons that a pharmacy chain
14 warehouse wanted a cage and vault structure to -- was
15 to prevent abuse and diversion of the opioid products
16 that Mallinckrodt manufactured?

17 MR. TSAI: Objection to form and scope.

18 A. The pharmacy chains needed a cage and
19 vault in their distribution centers because of DEA
20 licensing requirements relative to the storage and
21 distribution of controlled substances. Those cages and
22 vaults are dictated by DEA and there are requirements
23 for what type of security has to be in place in order
24 to directly receive and distribute controlled substance

1 products.

2 Q. (By Mr. Ko) And in the context of this
3 e-mail, you had referred to Price Chopper being a
4 grocery outlet with a pharmacy located at the
5 groceries; is that correct?

6 A. Yes, that's correct.

7 Q. And by the way, where were Price Chopper
8 stores located in the United States?

9 A. I am not familiar with all of the
10 locations of Price Chopper stores. I do know that they
11 had stores located in Missouri and other midwestern
12 states, but I don't know all of the states
13 specifically.

14 Q. You can set that aside. I'm now going to
15 hand you a copy of what will be marked as KV Exhibit
16 10.

17 [Exhibit Mallinckrodt-Vorderstrasse-010
18 marked for identification.]

19 Q. KV Exhibit 10 is an e-mail chain with
20 Bates-stamp MNK-T1_0001958991. And this represents an
21 e-mail chain between Randy Meisner -- or from Randy
22 Meisner and several other people, including once again
23 yourself. And it's dated November 8th, 2012. We had
24 talked about Randy before, but in terms of the other

1 people that are involved in this e-mail, including
2 yourself, how frequently did you meet to discuss
3 financial forecasts of the generic line of business?

4 A. The frequency with which we would have met
5 to discuss financial forecasts would have varied, but
6 at a minimum once a month we would have discussed
7 financial forecast.

8 Q. And generally speaking, the people
9 involved in this e-mail -- what departments did they
10 represent? Are these all people within the generic
11 line of business at Mallinckrodt, or are there people
12 on here from other segments of Mallinckrodt's business?

13 A. No, all of these people are -- were
14 involved in the generic business unit at that time.

15 Q. And you said that you would meet at least
16 once a month. Were there circumstances in which you
17 would meet more frequently than that?

18 A. We may have met on several occasions,
19 several separate meetings, to discuss the financial
20 forecast as part of the normal monthly update cycle for
21 financial forecasts. So in other words, it may have
22 taken us more than one meeting to work through
23 everything that we needed to discuss.

24 Q. And what role did you play in the creation

1 and/or input of any of these financial forecasts?

2 A. So at this time I was a product manager,
3 and I would provide unit volume sales forecasts and
4 price forecasts for the products for which I was
5 responsible for so that those could be rolled up in the
6 forecasting process.

7 Q. And who were these results generally
8 shared with?

9 A. The results of the forecasts were shared
10 with the operations and planning teams to drive
11 production scheduling. They were also shared with
12 business management to review the state of the
13 business, and on a quarterly basis forecasting results
14 were shared with senior management at the level above
15 the general manager of the business.

16 Q. You can set that aside. I want to switch
17 gears to a different topic. Is it correct to say that
18 Mallinckrodt employed sales reps to market and sell its
19 prescription opioids?

20 A. Mallinckrodt employed sales
21 representatives to market and sell our prescription
22 branded opioids. We employ national account managers
23 to contract for the sale of our generic prescription
24 opioids to wholesalers and pharmacy chains.

1 Q. Did you ever employ national account
2 managers to contract for the sale of branded
3 prescription opioids?

4 A. We had a national account trade team which
5 negotiated the wholesaler fee-for-service agreements
6 for distribution of the branded products through
7 wholesalers.

8 Q. And approximately how many sales reps did
9 Mallinckrodt employ to market and sell Mallinckrodt
10 prescription branded opioids?

11 A. Over time, the number ranged from 50 to
12 about 200 sales reps for branded opioids. They were --
13 there were always multiple products to -- for those
14 sales representatives to market. Those weren't always
15 all opioid products.

16 Q. With respect to the national account
17 managers that Mallinckrodt contracted for the sale of
18 the generic prescription opioids, approximately how
19 many did Mallinckrodt employ or utilize over the
20 relevant time period?

21 A. Over the relevant time period, the size of
22 the team has changed. At the -- at its largest, I
23 believe the national accounts team was about seven or
24 eight people for the generic products, and at its

1 smallest the team has been four.

2 Q. So in other words, there were seven or
3 eight people at its peak that were primarily
4 responsible for marketing Mallinckrodt's generic
5 opioids?

6 A. Seven or eight people who were primarily
7 responsible for direct contact with wholesaler and
8 pharmacy chain customers and negotiating agreements
9 with those customers.

10 Q. So -- and thank you for that answer. So
11 then is it fair to say when we're talking about
12 generics the primary way in which Mallinckrodt was able
13 to gain the market share that we were discussing before
14 was through its negotiations and communications with
15 distributors and pharmacies?

16 A. So in general terms, generic products,
17 whether opioid or non-opioid, are sold primarily based
18 upon price and also based upon quality and service, so
19 ability to supply, ability to supply consistently with
20 high-quality product is essential for generic
21 companies, but as near commodity products, ultimately
22 the price is often a deciding -- a key deciding factor
23 for wholesalers and pharmacy chains.

24 Q. And so with respect to the price,

1 isolating that separate and apart from quality and
2 service, was there any type of marketing done to --
3 directly to the pharmacies or distributors with respect
4 to Mallinckrodt products, or was it simply a price that
5 Mallinckrodt set and you had distributors essentially
6 take it or leave it?

7 A. The prices for our products were always
8 negotiated between Mallinckrodt and the distributor or
9 wholesaler or the pharmacy chain.

10 Q. And as you alluded to earlier, the primary
11 responsibility for the negotiation of these prices
12 rested with the national account managers; is that
13 correct?

14 A. National account managers were primarily
15 responsible for the negotiation effort. The product
16 management team was responsible for reviewing and
17 approving any prices that were offered and processing
18 that price through our contracting systems.

19 Q. And how did Mallinckrodt divide up these
20 negotiations with distributors and wholesalers? In
21 other words, let me ask it a different way. Was there
22 any distinction done by region with respect to the
23 negotiations Mallinckrodt had with respect to prices
24 vis-à-vis the distributors and the pharmacies?

1 A. Our negotiations for price and our
2 contracts for price with either wholesalers or with
3 pharmacy chains were considered to be company-wide, so
4 that those prices were available to the entire
5 wholesaler's business or the entire pharmacy chain's
6 business, not -- we never had anything that was
7 designated as specific to any given region.

8 Q. Got it. So just to make clear, there was
9 no adjustments made with respect to price based on a
10 particular region of where the distributor or the
11 pharmacy was located?

12 A. The geographical region of the location of
13 the distributor or pharmacy chain was not used in
14 setting price.

15 Q. So the price that would apply, for
16 example, in California, would apply with equal force to
17 a price that would be set in Ohio, for example?

18 A. To the extent that a customer sold in both
19 of those states, yes, absolutely.

20 Q. And can you -- turning -- or focusing
21 again on the national account managers, can you
22 describe to the court the general structure of that
23 team? So we had national account managers at the top.
24 Who were the types of people and/or categories of

1 people that were below them?

2 A. So the general structure of our national
3 accounts team, we always had a leader of that team,
4 often -- usually a vice-president. Below that were
5 either national account managers or national account
6 directors, and occasionally we had more junior
7 employees who were hired into that team as what we
8 termed regional account managers.

9 By regional account manager, that was not
10 to signify that they had a particular region of the
11 country, but that the customers that they dealt with
12 tended to be smaller customers and typically weren't
13 nationwide customers but typically were regional-type
14 customers.

15 Q. And can you give the court a general
16 understanding of the approximate size of this group of
17 national account team members?

18 A. So again, for the generics business, this
19 was a team that at minimum had three national account
20 directors and at most had seven or eight manager- and
21 director-level people.

22 Q. And then in terms of the -- just once
23 again trying to get an understanding of the overall
24 structure of this team. You said that there were also

1 some junior people that were brought in. How many more
2 people are we talking?

3 A. That would encompass the junior people --
4 that seven or eight number.

5 Q. Thank you. Going back to your testimony
6 earlier about the important drivers of these
7 discussions with distributors and pharmacies being
8 price, quality, and service, with respect to the latter
9 two categories, quality and service, what types of
10 marketing, if any, did Mallinckrodt do for those two
11 factors?

12 A. Relative to our generic products over time
13 we occasionally created either physical marketing
14 materials which could be handed out at trade shows or
15 typically very similar materials which were published
16 in trade periodicals which talked very briefly about
17 the structure of Mallinckrodt, our history in the
18 marketplace, how we handle planning supply and
19 communicating with customers -- things of that nature.

20 Q. So when we're talking quality and service,
21 we're talking quality and service of the Mallinckrodt
22 business from, I guess for lack of a better term, an
23 administrative perspective, and not necessarily the
24 quality and service of the underlying drugs in which

1 you were manufacturing? Is that fair to say?

2 A. Well, we communicated about our business
3 relative to how we ran the business, how we managed the
4 business, to help customers understand that the
5 products that they purchased from us would meet the
6 quality standards and would be supplied at the time
7 frame that they needed that product. So if a
8 wholesaler placed an order with us, we wanted them to
9 be confident that they were going to get that order
10 when they wanted it.

11 Q. Did Mallinckrodt do any marketing with
12 respect to the risks of its generic marketing or
13 generic opioid products?

14 A. For any product-specific marketing
15 materials that we put together for our generic
16 products, opioid or not, any warning information, risk
17 information that was included in the FDA-approved
18 labeling materials was included in the marketing
19 materials, and those materials were always reviewed to
20 ensure that they were current.

21 Q. And outside of the FDA-approved labeling
22 materials, was there any other additional marketing
23 materials that Mallinckrodt provided with respect to
24 its generic products?

1 A. Mallinckrodt never provided
2 product-specific marketing materials for our generic
3 products which contained any information other than
4 what was approved relative to the product or what was
5 specific to our company.

6 Q. Turning back to the sales reps that
7 Mallinckrodt utilized for purposes of its brand
8 products, approximately how many sales reps did
9 Mallinckrodt employ over the relevant time period with
10 respect to its branded opioids?

11 A. So relevant to branded opioids, at the
12 smallest that sales team was approximately 50 reps and
13 at its largest was about 200.

14 Q. And earlier we talked about Exalgo.
15 Approximately how many reps did Mallinckrodt utilize
16 with respect to marketing Exalgo from the 2009 through
17 2014 -- or was it 2015 that it discontinued?

18 A. I believe 2014 was when we discontinued
19 marketing efforts.

20 Q. So let me start so the record is clear.
21 So from the 2009 to 2015 time period how reps -- sales
22 reps did Mallinckrodt utilize to market Exalgo?

23 MR. TSAI: I'm going to object to the
24 form.

1 A. During that period, at peak, fifty --
2 about 200 sales reps were assigned to market Exalgo.

3 Q. (By Mr. Ko) And same question with
4 respect to Xartemis. The -- how many sales reps did
5 Mallinckrodt utilize to market Xartemis?

6 A. I don't know the exact number, and we only
7 sold that product for a short period of time, but I
8 believe we had no more than 50 sales reps on Xartemis
9 at any given time.

10 Q. "Xar-temis." I promise I'll say it
11 correctly.

12 A. It took us a long time too.

13 Q. And did Mallinckrodt distinguish by
14 territory or by region in the country -- strike that.
15 Were the sales reps divided by region or territory at
16 all?

17 A. The sales reps on the branded products
18 were assigned territories throughout the country that
19 were generally confined to one geographic area.

20 Q. And were there differentiations between
21 Exalgo and Xartemis, or was it the -- were the
22 territories generally the same for both products?

23 A. The territories -- well, the period of
24 marketing for those two products did not overlap, and

1 the sales territories were changed and reevaluated on
2 an annual basis, and I can't say for certain that there
3 weren't any territories that were identical from one
4 product to the next.

5 Q. And who was responsible for reevaluating
6 the territories on an annual basis?

7 A. We had a marketing analytics team on the
8 branded business that was specific to the branded
9 business which was responsible for coming up with sales
10 territories and selling targets which were then
11 approved by the sales and marketing management teams.

12 Q. Now, in terms of the training of the sales
13 reps assigned to market branded products, can you
14 describe to the court what the general training
15 protocol was?

16 A. So the general training protocol for the
17 branded sales reps involved product-specific training
18 so that they understood the features of the product,
19 they understood the FDA-approved labeling, the
20 indications, the risks, and the warnings, and then they
21 were also trained specifically on marketing materials
22 and other sales aids which were created for them, and
23 finally they were trained in general on many of the
24 same corporate-wide training initiatives that we have

1 relative to code of conduct, business ethics, as well
2 as industry guidelines on health care practitioner
3 interactions.

4 Q. And who was responsible for training the
5 sales reps with respect to the risks and the warnings
6 of the branded opioid products Mallinckrodt
7 manufactured?

8 A. Over time that changed, but we generally
9 had a training department who was responsible for that.

10 Q. And who was -- describe to the court who
11 these individuals were at the training department.

12 A. These were individuals who had subject
13 matter expertise in how to conduct training of sales
14 teams, and they coordinated that sales effort -- or
15 that training effort of the sales team -- sorry -- and
16 handled the documentation of the training.

17 Q. And so were these individuals Mallinckrodt
18 employees, or were they third parties or consultants
19 that Mallinckrodt utilized to train?

20 A. From time to time it could have been both.
21 In general we had Mallinckrodt employees who were
22 responsible for the training effort, but they may have
23 hired outside experts for certain topics.

24 Q. And so going back specifically to the

1 risks and warnings that were associated with some of
2 the Mallinckrodt branded opioid products, who was
3 specifically responsible for training sales reps with
4 respect to the risks and warnings?

5 MR. TSAI: I'll just object as to scope.
6 I think this is getting a bit outside the sales
7 compensation topic. But go ahead.

8 A. So I have not prepared to be able to
9 answer specifics about who was responsible for what
10 aspect of training.

11 Q. (By Mr. Ko) And how -- earlier you were
12 describing the general training protocol. Can you give
13 the court an understanding of how long it took for
14 Mallinckrodt to train sales reps?

15 MR. TSAI: Same objection as to scope.

16 A. Yeah, I do not have direct knowledge of
17 the length of time the training program took and not --
18 I have not prepared on the specifics.

19 Q. (By Mr. Ko) Who -- which department at
20 Mallinckrodt or what individuals would have the most
21 knowledge about the training that Mallinckrodt did of
22 its sales reps?

23 MR. TSAI: Objection as to scope.

24 A. The trained department we had in place at

1 that time has been dissolved, and most of the people
2 who were involved with the branded business are no
3 longer with the company, so I'm not sure who to point
4 you to to be able to address that.

5 Q. (By Mr. Ko) And when was it dissolved?
6 You said the training program was dissolved. Was it
7 the same time period that Xartemis and Exalgo came off
8 the market?

9 A. When we ceased marketing Xartemis in or
10 around 2015, we dissolved the branded opioid sales team
11 and many of the related functions.

12 MR. TSAI: We've been going about an hour
13 since the lunch break. Could we take a quick break?

14 MR. KO: Sure.

15 MR. TSAI: Thanks.

16 MR. KO: I actually need to take a break
17 myself.

18 THE VIDEOGRAPHER: We are going off the
19 record at 1:41 PM.

20 [A brief recess was taken.]

21 THE VIDEOGRAPHER: We are back on the
22 record at 1:50 PM.

23 MR. TSAI: So I think we've been going
24 about three-and-a-half hours on the record. Of course,

1 under the governing protocol for 30(b)6 depositions,
2 the time limit in aggregate for a 30(b)6 deposition
3 with more than one designee, as in this case -- we have
4 three -- is 14 hours on the record. This is not a
5 personal percipient witness deposition, so there's no
6 production of an individual custodial file. The topics
7 for which Mr. Vorderstrasse is designated are not
8 specific to any state in particular, with respect to
9 Tennessee, and Tennessee state counsel has not provided
10 any specific 30(b)6 or company witness topics after
11 receiving the cost notice.

12 So our position is that the deposition
13 protocol, Section 2A, which provides that examining
14 counsel shall confer prior to the deposition concerning
15 allocation of time to question a deponent, and that
16 counsel's failure to allocate time among themselves or
17 to enforce that allocation of time among themselves
18 during a deposition shall not constitute grounds to
19 extend a deposition. All that, given the 14-hour
20 limit, we believe that applies in this case, and just
21 wanted to state our position for the record.

22 MR. KO: And Tricia, I know you'll
23 probably respond and say something for the record, but
24 other than Section 2A of the deposition protocol,

1 Rocky, is there any other provision that you can point
2 to that justifies your position or is that based solely
3 on your interpretation of 2A?

4 MR. TSAI: Yeah, I don't think we have an
5 agreement specifically with respect to Tennessee
6 counsel as we did with the percipient depositions that
7 have occurred before that would apply to this --
8 today's 30(b)6 deposition.

9 MR. KO: Okay. Well, our position is
10 that -- at least the plaintiffs in the MDL firmly
11 believe that any time given to a state court party
12 should not be accounted for in the 14-hour limit that
13 is provided for in this situation, and in addition I'll
14 note for the record that there is nothing in the
15 provisions of deposition protocol, Section 4, that talk
16 about dividing up the time in that manner. I'll also
17 note that -- I believe in this case Mallinckrodt
18 cross-noticed this 30(b)6 deposition; is that correct?

19 MR. TSAI: We did provide a cross-notice
20 in the Tennessee state cases and providing the topics
21 listed in the deposition notice, again, none of which
22 we believe are Tennessee-specific.

23 MR. KO: Okay. And it's my understanding
24 that the plaintiffs in the Tennessee case did not

1 cross-notice this deposition.

2 MS. HERZFELD: We did not, no. We intend
3 to take our own 30(b)6 in our state case at a time
4 that's relevant for us.

5 MR. KO: Okay.

6 MS. HERZFELD: We're here because we were
7 cross-noticed by Mallinckrodt.

8 MR. KO: Okay.

9 MS. HERZFELD: And I intend to take my
10 time today. I will also just make a point of letting
11 counsel know that we have exchanged a significant
12 number of e-mails back and forth letting counsel know
13 that we intended to participate today, that we intended
14 to take our two hours if necessary that would be in
15 addition to the time allocated to the MDL and not to be
16 shared to the MDL of your total 14 hours.

17 We weren't even aware of a total 14 hour,
18 because we're not involved in the MDL. You all
19 cross-noticed us. I am here. It is now after lunch at
20 2:00 PM and this is the first time somebody has brought
21 up such an allocation issue, so we will certainly be
22 reserving our rights, and I intend to question the
23 witness today.

24 MR. KO: All right. And I would just add

1 that this is also the first time, at 2:00 PM on the day
2 of the deposition, that we were notified by
3 Mallinckrodt and opposing counsel that they are taking
4 the position that somehow a state case would impact or
5 have an effect on the 14-hour time limit clearly
6 provided to the plaintiffs in the MDL, so we highly
7 disagree with the fact that any time should be taken
8 away from the 14-hour limit provided by the court.
9 Ready to move on?

10 MR. TSAI: Yes.

11 Q. (By Mr. Ko) Kevin, I'm going to -- well,
12 the court reporter's going to hand you a copy of what's
13 going to be marked as KV Exhibit 11.

14 [Exhibit Mallinckrodt-Vorderstrasse-011
15 marked for identification.]

16 Q. Kevin, this is a copy of KV Exhibit 11,
17 Bates MNK-T1_0000090085, and this appears to be a sales
18 incentive compensation plan for sales reps at Covidien
19 for the fiscal year 2013. Is that a fair
20 characterization of this document?

21 A. I would clarify in that this applies to
22 branded sales representatives.

23 Q. Sure. So with respect to the branded
24 sales representatives, which is here delineated as

1 Specialty Pharmaceuticals, this is the sales incentive
2 compensation plan that governs their marketing of
3 branded -- Mallinckrodt branded opioids; is that
4 correct?

5 A. This governs the sales incentive
6 compensation for those sales representatives for the
7 branded opioids.

8 Q. By the way, do you recognize this document
9 at all?

10 A. Yes, I do.

11 Q. Have you seen it before?

12 A. Yes.

13 Q. And obviously this is with respect to
14 2013. Did Covidien and/or Mallinckrodt have similar
15 plans for other years in which it sold and manufactured
16 branded pharmaceutical opioids?

17 A. Yes, that is my understanding. The sales
18 incentive plans were generally similar from year to
19 year.

20 Q. And we discussed before the notion that
21 the branded sales reps would market not just opioids
22 but other branded products as well. Do you remember
23 that?

24 A. Right, our branded sales representatives

1 were charged with marketing a number of products; some
2 of them were non-opioid.

3 Q. And in this context, if you look at Page
4 5, some of those non-opioid products are mentioned; is
5 that correct?

6 A. Yes, that is correct.

7 Q. And what are those products?

8 A. In this document it looks like Pennsaid
9 and Duexis and Sumavel.

10 Q. And then there's also a reference to a
11 NSAID bucket. Do you see that?

12 A. Correct.

13 Q. And then those are painkillers but not
14 opioids; is that correct?

15 A. NSAIDs are non-opioid pain drugs of which
16 Pennsaid and Duexis were NSAIDs.

17 Q. And was Sumavel an NSAID as well?

18 A. I do not recall if it was or not.

19 Q. By the way, who was responsible for
20 creating this plan?

21 A. This plan was to my knowledge created by
22 the commercial analytics team for the branded business
23 with help from sales leadership.

24 Q. And if you look at Page 8 and 9 of this

1 plan --

2 A. Uh-huh.

3 Q. -- there's basically a weighting going on
4 to determine the compensation of a sales rep. Do you
5 see that?

6 A. Yes.

7 Q. Is it fair to say that the primary weight
8 is given to Exalgo or the lone prescription opioid in
9 this bundle of Mallinckrodt products?

10 A. It appears that for the four weightings
11 distributed or presented, Exalgo has the highest
12 percentage in all four.

13 Q. And that percentage ranges anywhere from
14 between -- for the record, between 50 and 60 percent?

15 A. Yes, that's correct.

16 Q. And sorry to jump around --

17 A. Uh-huh.

18 Q. -- but to go back to Page 3 of this
19 document titled key facts. There's references to TRxs.
20 Can you describe to the court and clarify what that
21 stands for?

22 A. Yes. So TRxs is a pharmaceutical industry
23 term likely coined by IMS which is an abbreviation for
24 total prescriptions.

1 Q. And with respect to total prescriptions,
2 it's clear that at least one primary metric that
3 determined a sales representative's compensation was
4 the amount of total prescriptions of Exalgo it had
5 managed to convince a physician to prescribe. Is that
6 correct?

7 A. So the sales compensation plan and the
8 sales representatives were compensated for the
9 incentive portion of their compensation based upon the
10 number of prescriptions which were written by their
11 targeted physicians for the products that were included
12 in their targeting plan.

13 Q. And the way in which Mallinckrodt was able
14 to track this information was through its purchase of
15 IMS data; is that correct?

16 A. IMS data allowed us the visibility into
17 prescription patterns for our products.

18 Q. And specifically it allowed Mallinckrodt
19 to understand the level of detail at the
20 physician-patient -- strike that. The IMS data allowed
21 Mallinckrodt to understand at the physician-patient
22 level the amount or prescriptions that the prescription
23 was issuing of Mallinckrodt products? Is that a fair
24 statement?

1 A. No, that's not correct. The IMS data
2 allowed us to see the number of prescriptions which
3 were dispensed which had been written by a given
4 physician. We had no visibility into who the patients
5 were, who received those prescriptions.

6 Q. Fair enough, and I certainly wasn't
7 meaning to suggest that, so thank you for that
8 clarification. Other than the IMS data and as it
9 pertains to the compensation structure of the sales
10 representatives, did Mallinckrodt otherwise track the
11 total amount of prescriptions of Exalgo that these
12 sales reps were able to have the physicians prescribe?

13 MR. TSAI: Object to the form of the
14 question.

15 A. Mallinckrodt tracked the total number of
16 prescriptions dispensed for Exalgo, as well as tracking
17 those prescriptions based upon which prescribers wrote
18 those prescriptions.

19 Q. (By Mr. Ko) And when you say Mallinckrodt
20 tracked the total number of prescriptions dispensed for
21 Exalgo, how did they do that?

22 A. Mallinckrodt analyzed IMS data, Xponent
23 data, which provided us the identity of physicians or
24 other prescribers who were prescribing the products and

1 associated those prescriptions with those prescribers.

2 Q. Other than the IMS and Xponent data, were
3 there any other sources of information Mallinckrodt
4 utilized in order to track the total number of
5 prescriptions dispensed of Exalgo?

6 A. I'm not aware of any other data sources we
7 would have used.

8 Q. And with respect to tracking the
9 prescriptions based upon which prescribers wrote Exalgo
10 prescriptions, did Mallinckrodt also similarly utilize
11 IMS and Xponent data to gather that information?

12 A. IMS data was used by Mallinckrodt to
13 determine the number of prescriptions for any given
14 product written by individual physicians in the sales
15 territories.

16 Q. And the total number of prescriptions
17 dispensed for Exalgo was a primary factor or a primary
18 basis for which sales reps were compensated; is that
19 correct?

20 A. Sales representatives received incentive
21 compensation for achieving or exceeding the
22 prescription targets which were developed for the
23 physicians in their territory. That incentive
24 compensation was generally a small portion of their

1 total compensation. 10 to 25 percent approximately of
2 a sales representative's total compensation could come
3 from the incentive plan.

4 Q. And the remaining 75 to 90 percent -- what
5 did that consist of?

6 A. That was a base salary.

7 Q. And so other than the base salary, then
8 the 10 to 25 percent we're talking about a bonus- or
9 commission-type structure; is that correct?

10 A. The -- it was a bonus structure based on
11 achieving certain defined targets. Our sales
12 representatives were never commissioned on a
13 per-activity or per-script basis.

14 Q. So in terms of the 10 to 25 percent that
15 represented the bonus of a sales rep's compensation,
16 was any of that 10 to 25 percent based on anything
17 other than the total amount of prescriptions of Exalgo?

18 A. Yes, the bonus was also partially derived
19 from achieving prescribing results for the other
20 products that they were designated to represent,
21 Pennsaid, Duexis, and Sumavel in this plan.

22 Q. But as we discussed before, Exalgo made up
23 the primary portion of that calculus, for lack of a
24 better term; correct?

1 A. Exalgo made up the largest percentage of
2 the weighting of any given sales representative's
3 territory, but the individual payout was based upon the
4 attainment for all four products. To the extent that
5 Exalgo may not have been as successful in a given
6 territory, Exalgo may not have driven the incentive
7 comp for that sales rep.

8 Q. And earlier when you described targeting
9 of physicians -- who determined which physicians to
10 target?

11 A. Again, our commercial analytics team who
12 reviewed the Xponent data. They developed the
13 territories and the targets, sometimes with the
14 assistance of outside consulting firms and always with
15 the input of sales management.

16 Q. And with respect to the marketing of
17 Exalgo in particular, were there any other groups other
18 than the commercial analytics team that determined
19 which doctors to target?

20 A. On occasion we used outside consulting
21 firms to assist in that process.

22 Q. And who was in charge of the commercial
23 analytics team at the time that Exalgo was marketed?

24 A. I am not 100 percent sure who was in

1 charge at that time, and I believe it changed during
2 that period.

3 Q. Turning to -- oh, it changed in what
4 sense? That the individual --

5 A. The individual changed.

6 Q. I see.

7 A. Management changed.

8 Q. I'm turning to Page 6 of this plan.
9 There's a reference to Special Achievement Award. Do
10 you see that?

11 A. Yes.

12 Q. And do you have any understanding of who
13 is responsible for making that determination of who
14 received the Special Achievement Award?

15 A. It's my understanding that that award was
16 given out based upon the collective opinion of sales
17 management.

18 Q. And it was given to a sales rep based on
19 their performance, including total prescriptions sold
20 of Exalgo; correct?

21 A. Well, as this specifies, this is in
22 recognition for behavioral excellence and for
23 demonstrating the behaviors that we were seeking in our
24 sales representatives as good representatives of the

1 company. The amount of weight or the amount that
2 prescription performance factored into these is not
3 clear from this document, and I would conclude it
4 was -- had very little impact on these awards.

5 Q. Was there any monetary amount in
6 connection with this Special Achievement Award provided
7 to the sales rep?

8 A. As outlined here, the sales
9 representatives could receive no more than \$2,500 for a
10 single award, and it appears that they were designed to
11 most often be \$1,500 awards.

12 Q. I'm going to now hand you a copy of what's
13 going to be marked as KV Exhibit 12.

14 [Exhibit Mallinckrodt-Vorderstrasse-012
15 marked for identification.]

16 Q. The court reporter has handed you Exhibit
17 12, which is a cover e-mail containing three
18 attachments. And for the record, the e-mail is located
19 at MNK-T1_0000538136. There's a cover e-mail from
20 Terese Lafeber to Stacy Chick, CCing some others, and
21 there are some sales compensation plans attached to
22 this. Do you see that, Kevin?

23 A. Yes, I do.

24 Q. And in particular, it appears that there

1 are three sales compen -- sales incentive compensation
2 plans attached to this e-mail. Do you recognize these
3 documents at all?

4 A. I recognize them in general. I don't
5 believe I've reviewed these specific documents.

6 Q. Is it fair to say that these -- well,
7 let's start with the first one. The first one appears
8 to be a sales incentive compensation plan for a
9 regional sales director of the brand department at
10 Mallinckrodt; is that correct?

11 A. Yes, I have that one.

12 Q. And that's for the time period October
13 2014 through December 2014?

14 A. That's correct.

15 Q. And this particular plan is only for a
16 time period of three months, whereas the plan we looked
17 at before was a time period of a year. Did
18 Mallinckrodt have plans that were -- it looks like
19 Mallinckrodt had plans that were less than one year
20 with respect to its sales incentive package; is that
21 correct?

22 A. Based upon this document, that appears
23 correct.

24 Q. And do you know -- do you have any

1 understanding of how frequently over the course of a
2 year it changed its sales incentive plans? Was it
3 quarter -- was it no more than quarterly, or was it
4 more frequent than that?

5 A. In general, sales incentive plans were
6 annual plans. I am not aware of any changes more
7 frequently than a quarterly update.

8 Q. And the three documents together are sales
9 incentive plans with respect to regional sales
10 directors. All three of them relate to regional sales
11 directors; is that correct?

12 A. It appears one is regional sales director,
13 one's district sales manager, and one's field sales
14 specialist.

15 Q. That's what I thought. I'm actually
16 looking at a different version, so thank you for that
17 clarification. And these are again all compensation
18 plans with respect to the branded portion amount of
19 Mallinckrodt's business; correct?

20 A. Correct.

21 Q. And is there a -- one moment here.

22 [Discussion off the record.]

23 Q. And going to field sales specialists, is
24 that another term that Mallinckrodt used for a sales

1 representative, or is there something different with
2 respect to a field sales specialist relative to a sales
3 rep?

4 A. It's my understanding that those terms are
5 interchangeable and that we changed to the field sales
6 specialist terminology most recently.

7 Q. And I believe there is some mention of
8 Xartemis in these documents. Is that correct?

9 A. Yes.

10 Q. So earlier we had talked about the sales
11 incentive plan with respect to Exalgo among other drugs
12 that Mallinckrodt manufactured. This appears to be a
13 sales incentive plan with respect to Xartemis, among
14 other drugs; is that correct?

15 A. This sales incentive plan covers Xartemis
16 and Pennsaid.

17 Q. Also mentioned Ofirmev, I believe, in one
18 of those documents. Actually, you can skip that.
19 That's not important. Let's turn to -- or strike that.
20 Before we had talked about how Mallinckrodt through its
21 commercial analytics team had divided up the country by
22 territory --

23 A. Uh-huh.

24 Q. -- with respect to Exalgo. I just want

1 to make sure that the answer applies with equal force
2 with respect to Xartemis. Was -- the same distinctions
3 done by the commercial analytics team with occasional
4 input from third parties apply with respect to Xartemis
5 as well?

6 A. My understanding is that sales territories
7 were generally developed in a similar manner for
8 Xartemis as they were for any of the other branded
9 products, so that field sales specialists in this case
10 had a designated territory generally in the same
11 geographic area that included a certain number of
12 specific physician targets.

13 Q. You can set that aside. I'm going to hand
14 you a copy of what's going to be marked as KV Exhibit
15 14.

16 THE REPORTER: Oh, it's 13, actually.

17 MR. KO: Oh, 13. Okay.

18 [Exhibit Mallinckrodt-Vorderstrasse-013
19 marked for identification.]

20 Q. (By Mr. Ko) And for the record this
21 exhibit is MNK-T1_0000259116, and it is titled
22 specialty generic sales incentive plan document for
23 fiscal year 2009. Do you recognize this document at
24 all?

1 A. I have not seen this particular document,
2 but I do generally recognize what it is.

3 Q. And earlier we had gone over some
4 specialty incentive plans for the branded drugs that
5 Mallinckrodt manufactures. Is it fair to say that this
6 is a sales incentive plan with respect to the generic
7 drugs that Mallinckrodt manufactures?

8 A. That appears to be correct.

9 Q. And earlier we had discussed the type of
10 marketing that was done by the generics department, and
11 if you look on page -- if you look on the second page
12 of this document, in purpose, it appears that the
13 purpose of this plan is to provide an incentive
14 opportunity to the specialty generic sales personnel,
15 as defined herein. Do you see that?

16 A. Yes, I do.

17 Q. And would these speciality generic sales
18 personnel be the national account managers that we were
19 discussing earlier today?

20 A. I would have to review the document to
21 understand exactly which personnel this applied to.

22 Q. Well, and the reason I ask is actually --
23 I was looking at it before. The definitions don't
24 actually define specialty generics sales personnel.

1 A. Okay.

2 Q. So I guess I can ask you generally,
3 separate from this document, was there a sales
4 incentive plan document that governed the compensation
5 structure of the national account managers for the
6 generic line of business at Mallinckrodt?

7 A. So it appears that that is farther back in
8 this document, beginning on Page -- I guess it's
9 effectively Page 5. I'm sorry. No. Page 6.

10 Q. Is that ending in Bates 18?

11 A. 121.

12 Q. Or excuse me.

13 A. Or 16.

14 Q. Excuse me. Yes. So the record is clear,
15 we are looking at MNK-T1_0000259126.

16 A. Well, I'm looking at 259121.

17 Q. Okay. Fair enough.

18 A. And this would appear to be the incentive
19 plan for the retail national account managers which
20 would cover the generic product sold to the retail
21 channel wholesalers and pharmacy chains.

22 Q. So the record is clear, Mallinckrodt had a
23 sales incentive compensation plan for its national
24 account managers; correct?

1 A. For its generic national account managers,
2 yes.

3 Q. And were there annual plans with respect
4 to the generic side of the business as well, or do you
5 recall if there were any more frequent plans than
6 annually?

7 A. My understanding is it was always an
8 annual plan.

9 Q. And if you turn to the page before the one
10 you're looking at that's ending in Bates 120, there's
11 also an incentive plan for national account managers
12 with respect to addiction treatment sales. Do you see
13 that?

14 A. Yes.

15 Q. And so that governs the sale of the
16 various forms of addiction treatment for opioid use
17 disorder we were discussing earlier today; correct?

18 A. This would cover the national account team
19 which called on addiction treatment clinics, primarily
20 methadone clinics, and specifically sold products into
21 that channel.

22 Q. At this time was it -- did Mallinckrodt
23 primarily manufacture a generic form of methadone in
24 terms of the addiction treatment products it was

1 manufacturing?

2 A. For our addiction treatment products, yes,
3 it was primarily methadone at that time.

4 Q. And when did Mallinckrodt first begin to
5 manufacture a generic version of methadone?

6 A. Mallinckrodt has been manufacturing
7 generic methadone since I believe the early 1970s.

8 Q. And does it still continue to manufacture
9 a generic version of methadone today?

10 A. Yes, we do.

11 Q. And do you have any understanding of what
12 market share Mallinckrodt generic methadone represents?

13 A. Our general understanding is that in the
14 addiction treatment, methadone addiction treatment
15 clinics, our product represents about 60 to 65 percent
16 of that overall market.

17 Q. Do you have any knowledge or did
18 Mallinckrodt acquire any knowledge about the abuse
19 potential of methadone?

20 A. To my knowledge we have never studied the
21 abuse potential of methadone.

22 Q. You can set that one aside. I'm going to
23 now hand you a copy of what's going to be marked as KV
24 14.

1 [Exhibit Mallinckrodt-Vorderstrasse-014
2 marked for identification.]

3 Q. For the record, KV Exhibit 14 is an e-mail
4 with an attachment from Kevin Becker to several
5 individuals from August 26, 2011, and the beginning
6 Bates is MNK-T1_004252956, and the attachment is a
7 branded sales rep incentive plan. Kevin, have you --
8 does this document look familiar to you at all?

9 A. No, this particular document does not.

10 Q. Is it fair to characterize the attachment
11 as the sales representative incentive plan for
12 Mallinckrodt branded products from 2009?

13 A. Yes, this appears to be the incentive plan
14 for the branded sales reps during that period.

15 Q. And if you look at the measure, there's a
16 list of several drugs. Exalgo and Xartemis are not
17 included here, but there's a reference to Magnacet. Do
18 you see that?

19 A. Yes, I do.

20 Q. Is Magnacet a branded opioid that
21 Mallinckrodt manufactured?

22 A. Yes, that is a branded opioid that we
23 manufactured at that time.

24 Q. And when did Mallinckrodt first

1 manufacture Magnacet?

2 A. I don't know the exact start date, but I
3 believe we began selling that product shortly before
4 this document would have been created, shortly before
5 fiscal 2009.

6 Q. So sometime approximately in the 2008 or
7 2009 time period was when Mallinckrodt first
8 manufactured Magnacet?

9 A. Approximately at that time, yes.

10 Q. And when -- and my understanding is that
11 Magnacet is no longer manufactured by Mallinckrodt. Is
12 that correct?

13 A. That is correct.

14 Q. When did Magnacet come off market?

15 A. It's my understanding that we only
16 marketed the product for a few years. I believe by
17 around 2011 we had already ceased marketing.

18 Q. By the way -- so we've gone over Exalgo
19 and Xartemis and now Magnacet. Were there any other
20 branded opioids that Mallinckrodt manufactured other
21 than those three?

22 A. The only other product that I am aware of
23 which contains an opioid is referenced in this
24 document. It's TussiCaps, and TussiCaps is a

1 prescription cough/cold product which combines
2 hydrocodone and an antihistamine, and it's used as a
3 cough suppressant.

4 Q. And that's -- is that a liquid version of
5 hydrocodone and codeine, I believe?

6 A. It is a capsule version, solid oral
7 version, of hydrocodone and chlorpheniramine.

8 Q. And when did Mallinckrodt first
9 manufacture TussiCaps?

10 A. On or around 2007, I believe.

11 Q. And when did Mallinckrodt take TussiCaps
12 off market?

13 A. We divested TussiCaps probably in around
14 the 2011 time frame.

15 Q. So other than Exalgo, Xartemis, Magnacet,
16 and TussiCaps, were there any other branded opioids
17 that Mallinckrodt manufactured?

18 A. Not to my knowledge.

19 Q. Going back to the cover e-mail from Kevin
20 Becker -- between Kevin Becker and Steven Sage -- who's
21 Kevin Becker?

22 A. I do not know for sure his title. I know
23 he was a manager in the sales team. I don't know if he
24 was a regional manager or a district manager.

1 Q. And there's a senior sales specialist at
2 Covidien also mentioned here, Steven Sage. Do you know
3 who he is?

4 A. I'm not aware of who he is.

5 Q. In the e-mail it describes his role, as we
6 said, senior sales specialist. It says Cleveland East.
7 Do you see that?

8 A. I do.

9 Q. Did Mallinckrodt -- or was Cleveland East
10 one of the territories that Mallinckrodt may have
11 designated in terms of the sales reps it had in the
12 country?

13 A. I don't have the specific information
14 around the sales territories at this time in order to
15 confirm, but I would conclude that that was to
16 represent his territory.

17 Q. Are you aware of any territories in Ohio
18 that Mallinckrodt had designated for -- in connection
19 with its manufacture of branded opioids?

20 A. I am aware that we had sales territories
21 in Ohio, but I don't know specifics.

22 Q. And generally speaking, how many sales
23 territories did you have in Ohio?

24 A. I don't know.

1 Q. Fair to say you at least had a Cleveland
2 East at some point?

3 A. That would appear to be correct.

4 Q. I am now going to hand you a rather
5 voluminous document, but this one is going to be marked
6 as KV 15.

7 [Exhibit Mallinckrodt-Vorderstrasse-015
8 marked for identification.]

9 Q. And because this is a native version, the
10 actual Bates-stamp is not on here, but I will represent
11 to everyone here that this document can be located at
12 MNK-T1_0000468961. And this document is a Covidien
13 2011-2015 strategic plan for its pharmaceutical sector
14 dated May 28th, 2010. Does this document look familiar
15 at all to you, Kevin?

16 A. This document looks generally familiar.
17 I'm not sure if I have seen the entire document in the
18 past.

19 Q. And when you say generally familiar, what
20 do you mean by that?

21 A. I am familiar with the general format and
22 some of the content because I recognize those from
23 other presentations over time. Since this was an
24 entire sector document, I would not have received this

1 entire document at the time and I haven't reviewed this
2 entire document in prep for this.

3 Q. Fair enough. In terms of the -- if you
4 look at the second page, there's a table of contents.
5 Do you see that?

6 A. Yes.

7 Q. And this document -- fortunately for you,
8 we're not going to go over each and every page, but
9 this document reveals a roadmap of the strategic --
10 among other things, the strategic imperatives of
11 Mallinckrodt's pharmaceutical segment. Is that
12 correct?

13 A. That appears correct, yes.

14 Q. And the pharmaceutical segment of course
15 includes, as we've been discussing all day, both
16 branded and generic arms of the Mallinckrodt business.
17 Is that fair to say?

18 A. Yes, that's correct.

19 Q. Among other things, this document is
20 capturing, as the roadmap suggests, enablers and key
21 initiatives of the pharmaceutical business of
22 Mallinckrodt. Is that correct?

23 A. I see that, yes.

24 Q. And it also is discussing the environment

1 and competitive context of the pharmaceutical sector
2 for Mallinckrodt; correct?

3 A. That's correct.

4 Q. And lastly, this document also details the
5 financial results and impact of Mallinckrodt's
6 pharmaceutical business; is that correct?

7 A. Yes.

8 Q. Turn with me to Page 21 of this document.

9 A. Okay.

10 Q. You see some references here made to Steps
11 1, 2, and 3?

12 A. Yes.

13 Q. You see that? And actually, before -- at
14 the top of the page there is a reference to U.S. WHO,
15 Steps 1 and 3. What's your understanding of what the
16 U.S. WHO is referring to?

17 A. So this is referencing to, from the view
18 of the United States market, the World Health
19 Organization's pain treatment steps and a breakdown of
20 the pain treatment market in the U.S. based upon those
21 steps.

22 Q. And -- thank you for that. And just so
23 the record is clear, WHO stands for World Health
24 Organization; correct?

1 A. Yes, that's correct.

2 Q. And can you give the court a general
3 description of what the Steps 1 through 3 entail?

4 A. So the World Health Organization's pain
5 ladder, as it was referred to, attempted to provide a
6 context for the treatment of pain generally targeted
7 towards cancer patients or others with chronic pain in
8 a stepwise fashion, so it talked about NSAIDs,
9 non-opioid, nonsteroidal antiinflammatories for the
10 treatment of minor pain. As pain escalated, it looked
11 at the use of weak opioids or opioid combination
12 products, and for the strongest pain, strong opioids.

13 Q. And Mallinckrodt had lines of business or
14 products in all three of these steps or categories; is
15 that correct?

16 A. Over time between the branded and generics
17 business we did cover all three steps.

18 Q. And currently is Mallinckrodt still
19 manufacturing drugs in each of these categories?

20 A. Mallinckrodt's generic business currently
21 manufactures and sells products which would fall under
22 Step 2 and Step 3. In terms of Step 1, we do not sell
23 any finished pharmaceuticals, brand or generic, that
24 fit in Step 1.

1 Q. So currently Mallinckrodt no longer
2 manufactures NSAIDs?

3 A. Not within SpecGX or the brand or generic
4 business that we've been talking about today. The
5 current branded business of Mallinckrodt does sell
6 Ofirmev, which you mentioned earlier, which would fit
7 in the Step 1 category.

8 Q. I see. And you also said in a previous
9 response that you -- in terms of Step 1, you do not
10 sell any finished pharmaceuticals. Are you referring
11 to the fact that Mallinckrodt actually purchases
12 bulk -- or purchases narcotics in its raw form?

13 A. No. Step 1 would include products such as
14 acetaminophen and ibuprofen. We do sell the bulk
15 active ingredient, acetaminophen and ibuprofen to
16 customers, as a bulk powder, not in a finished form.

17 Q. And that's what I was referring to.
18 You've been more articulate than I have. But in terms
19 of Step 1, just so the record is clear, currently
20 Mallinckrodt does not sell or manufacture a finished
21 NSAID product; is that correct?

22 A. Correct, in terms of the parts of the
23 business that I'm representing today, with the
24 exception of the branded Ofirmev acetaminophen product,

1 which is sold by our current branded business.

2 Q. And is -- what entity sells that product?

3 A. I believe that would fall under

4 Mallinckrodt LLC.

5 Q. And I just want to clarify because you

6 said that -- you are here speaking on behalf of the LLC

7 as well; correct? I thought we had established that

8 earlier today.

9 A. Yes. I should clarify that in terms of

10 the scope that I've been given, that product was not

11 included in the preparation.

12 Q. I see what you're saying. But

13 Mallinckrodt LLC manufactures Ofirmev, just so I

14 understand; is that correct?

15 A. And --

16 MR. TSAI: Object to the scope. Go ahead.

17 A. To be perfectly clear, Mallinckrodt LLC

18 markets Ofirmev; they technically do not manufacture

19 it.

20 Q. (By Mr. Ko) Fair enough. In terms of

21 these steps that are reflected here -- and this is of

22 course as of 2009, I believe -- around that time

23 period -- have these steps remained the same over time

24 by the World Health Organization?

1 A. I am not aware if the steps or the
2 definitions have changed since 2009.

3 Q. Fast-forward to Page 29. This appears to
4 be a summary of how Mallinckrodt prepares its sales
5 force. Is that fair to say?

6 A. This appears to be a summary of how we
7 built our branded sales force in the 2008-2009 time
8 period.

9 Q. And thank you for that clarification.
10 This obviously relates specifically to the branded
11 sales force, and it appears that at least according to
12 this document the goal was to higher approximately 150
13 sales reps for Mallinckrodt's branded segment. Is that
14 correct?

15 A. That appears correct, yes.

16 Q. And that appears to be from a pool of
17 approximately 15,000 résumés?

18 A. Yes, that looks correct.

19 Q. Do you know who was responsible for hiring
20 these sales reps?

21 A. I do not know the particular individuals
22 at this time who would have been responsible, but it
23 would have been the existing sales management with the
24 input of human resources and others within the

1 business.

2 Q. And who was the director of sales
3 management at this time? We're talking about in the
4 2009 to 2010 time period.

5 A. Yeah, I'm not sure who that was at that
6 time.

7 Q. Is there a manager of sales -- or is there
8 a director of sales management at this time at
9 Mallinckrodt?

10 A. So the sales organization that was in
11 place to sell these particular branded products has
12 been dissolved. There are sales organizations in place
13 to sell Mallinckrodt's other branded products that are
14 on the market today, but those are not the same teams.

15 Q. By the way, I know that -- so all the
16 branded opioids have been taken off market by
17 Mallinckrodt. Is Mallinckrodt currently developing or
18 thinking about manufacturing any additional branded
19 opioids?

20 MR. TSAI: Object to scope.

21 A. We are not in the process of preparing to
22 sell any new branded opioids.

23 Q. (By Mr. Ko) Going back to this document,
24 on the bottom left-hand corner, underneath eight

1 training modules, there's a reference to REMS. Do you
2 see that?

3 A. Yes.

4 Q. What's your understanding of REMS?

5 A. REMS is an FDA acronym for risk evaluation
6 and mitigation strategies.

7 Q. And who provided REMS training to these
8 sales reps?

9 A. I do not know who specifically provided
10 REMS training to the sales reps at this time.

11 Q. And with respect to the CARES Alliance,
12 what is that in reference to?

13 A. I am not completely familiar with CARES
14 Alliance other than I know that it was a compilation of
15 educational materials for others outside of the company
16 which we provided as a reference to our sales team at
17 the time.

18 Q. I see. And when you say others outside
19 the company, what do you mean by that?

20 A. It's my understanding this was an industry
21 or a reference document or reference program for health
22 care professionals and others within the pharmaceutical
23 industry, and we used those materials as well as
24 part -- as well for part of our training of our sales

1 employees.

2 Q. I see. And are you aware of any other --
3 strike that. Was Mallinckrodt a member of the CARES
4 Alliance as far as you know?

5 MR. TSAI: Object to scope.

6 A. Yeah, I do not know if we were a member.
7 I'm not prepared on that.

8 Q. (By Mr. Ko) Sure. Do you have any
9 understanding of any other entities that were part of
10 the CARES Alliance?

11 MR. TSAI: Object to scope.

12 A. No.

13 Q. (By Mr. Ko) And do you know who provided
14 the training to the sales reps on the CARES Alliance
15 training module that's identified here?

16 MR. TSAI: Object to scope.

17 A. No, I don't.

18 Q. (By Mr. Ko) Turn to the next page, 30.
19 It's titled creating new sales territories. And
20 obviously we talked about some of the sales territories
21 before. Here it indicates that there are approximately
22 250 territories designated by Mallinckrodt. Do you see
23 that reference?

24 A. Yes. Yes, I do.

1 Q. And that seems to be the sum of
2 territories that Mallinckrodt had designated for
3 Exalgo, Pennsaid, and a, quote/unquote, existing
4 territories category. Do you see that?

5 A. That -- yes, it appears to be the sum of
6 those three.

7 Q. And are these territories similar to the
8 territories we were describing -- or we were discussing
9 earlier in which you said the commercial analytics team
10 would reevaluate year after year or on an annual basis
11 how to divide up the country in terms of which regions
12 your sales reps would go to?

13 A. So I can't tell specifically from the
14 information provided here, but this general process
15 appears to align with the general process I described
16 in terms of how we set territories.

17 Q. And obviously this is before the
18 manufacture and sale of Xartemis, but did Xartemis add
19 to the territories that were designated by Mallinckrodt
20 or did Xartemis -- was Xartemis sold within the
21 existing territories that Mallinckrodt had designated?

22 A. So it's my understanding that over time we
23 reviewed our sales territories and our alignment on an
24 annual basis and made changes as needed, and so between

1 2009 and the launch of Xartemis, there could have been
2 many changes, and I can't say for certain if any of the
3 territories remained the same, but I am fairly certain
4 that we had fewer than 250 territories for Xartemis.

5 Q. So by the time two thousand and four -- by
6 the time we come to 2014 when Xartemis hits the market,
7 are you saying that there were no more than 250
8 territories total for the branded aspect of the
9 Mallinckrodt business, or are you saying there were
10 just no more than 250 territories for Xartemis in
11 particular?

12 A. So relative to the sales territories that
13 applied to the sales team that sold Xartemis, there
14 were fewer than 250 territories in total, which
15 included the territories that -- where Xartemis was
16 sold.

17 Q. I see. Thank you. Turn to Page 44 of
18 this document. And I know that you had obviously
19 testified that you don't know much about the CARES
20 Alliance --

21 A. Uh-huh.

22 Q. -- so I'm not going to ask you questions
23 about that, but I just have a specific question about
24 the bottom left-hand corner. It says one member of

1 IWG, regulatory perspective, REMS police. Do you see
2 that?

3 A. Yes.

4 Q. Do you have any understanding of what IWG
5 stands for?

6 A. IWG is typically a general three-letter
7 abbreviation for industry working group.

8 Q. And so this seems to be a reference to an
9 industry working group with respect to the REMS that we
10 were just discussing before?

11 MR. TSAI: Object to scope.

12 A. Without more detail -- talking points
13 behind this slide, I'm not sure what it's saying.

14 Q. (By Mr. Ko) And at any time in which
15 Mallinckrodt manufactured opioids, do you recall which
16 working groups or industry working groups Mallinckrodt
17 may have been a part of?

18 MR. TSAI: Object to scope and form.

19 A. No, I don't know specifics over time of
20 our industry working groups.

21 Q. (By Mr. Ko) Does the acronym ADIWG ring a
22 bell to you at all?

23 A. Did you say ADI?

24 Q. Correct. ADIWG.

1 A. No. I'm not sure I know what that is.

2 Q. By the way, on the second page there's a
3 reference on the right-hand column to Ruby, Zircon, et
4 cetera. Do you see that?

5 A. Yes.

6 Q. What is Ruby in reference to?

7 A. Ruby was the code name during the
8 development period for Xartemis.

9 Q. And how about Zircon?

10 A. Zircon was the code name for a similar
11 product to Xartemis which ultimately was abandoned and
12 never launched.

13 Q. And was that -- is that a product that's
14 also referred to as MNK-155 internally at Mallinckrodt?

15 A. I believe that's the correct number.

16 Q. And what were the primary differences
17 between Xartemis and the MNK-155?

18 A. Xartemis was a combination of oxycodone
19 and acetaminophen. MNK-155 was hydrocodone and
20 acetaminophen with a similar technology and dosage
21 form.

22 Q. And were they both extended release?

23 A. Yes, they were.

24 Q. And with respect to Exalgo, that's also

1 extended release; correct?

2 A. Yes, Exalgo's extended release.

3 MR. KO: Can we actually take a quick
4 break?

5 MR. TSAI: Sure.

6 THE VIDEOGRAPHER: We are going off the
7 record at 2:53 PM.

8 [A brief recess was taken.]

9 THE VIDEOGRAPHER: We are back on the
10 record at 3:10 PM.

11 Q. (By Mr. Ko) Kevin, thank you for your
12 patience throughout this day. I see you still have
13 that document in front of you and I'll ask that you
14 keep it there because we're going to refer to it again,
15 but I want to follow up on some questions -- or I want
16 to follow up on a discussion we had earlier today about
17 the sales reps and their interactions with physicians.
18 What sort of directions or guidelines did Mallinckrodt
19 have for the sales representatives of its branded
20 opioids?

21 A. Mallinckrodt had a training process where
22 we reviewed our sales aids with the sales team to help
23 them understand both the content and the appropriate
24 use of those sales aids.

1 Q. And can I interrupt you just right now, or
2 right here? So what do you mean by sales aids?

3 A. At various different times we had
4 documents or pamphlets or iPad applications which were
5 used to review product information with physicians
6 during a sales visit. The sales team was trained on
7 how to use those materials and the proper way to
8 communicate with physicians, including ensuring that
9 they stayed on message, that they understood the proper
10 way to discuss the labeling, and that they were aware
11 of how to handle questions that they were unable to
12 answer.

13 Q. And who determined the content of the
14 sales aid?

15 A. The content of the sales aid was typically
16 determined by the marketing team.

17 Q. And did you have any direct involvement in
18 that?

19 A. I did not.

20 Q. And in terms of the sales aids being
21 shared with physicians, were there any sales aids for
22 patients?

23 A. I am not aware of any specific sales aids
24 for patients. The FDA-approved labeling included at

1 different times a medication guide or other patient
2 instructions which were meant to be given to patients
3 by pharmacies so that they would understand the details
4 about using the product.

5 Q. Did Mallinckrodt do any marketing of its
6 branded opioid drugs to patients directly?

7 A. No, we did not market any branded products
8 to patients directly.

9 Q. And other than sales aids and/or other
10 marketing material to physicians, did Mallinckrodt
11 provide any marketing material to the public at large?

12 A. Mallinckrodt did not advertise to the
13 public at large regarding our products or in general
14 terms.

15 Q. And going specifically back to sales aids,
16 were there any other categories of people or entities
17 that Mallinckrodt prepared sales aids for other than
18 physicians?

19 A. I am not aware of any specific sales aids
20 for anyone else.

21 Q. And what types of reports or databases
22 were utilized to share the results of the sales reps'
23 performance in their communications with physicians?

24 MR. TSAI: Object to form.

1 A. So the sales representatives were provided
2 reports and access to reports on their -- on the
3 prescription results from their territories so that
4 they could understand if they were hitting their
5 targets for their incentive plan for that year, and
6 that was all IMS Xponent data.

7 Q. (By Mr. Ko) And who typically prepared
8 those reports?

9 A. That was again prepared by the commercial
10 analytics team.

11 Q. Based again on the IMS Xponent data?

12 A. Yes, that's correct.

13 Q. Exclusively, or primarily?

14 A. To my knowledge, exclusively.

15 Q. Other than those reports, were there any
16 other measures of performance that Mallinckrodt
17 provided to its sales reps regarding the prescriptions
18 of Mallinckrodt opioids?

19 A. Not to my knowledge.

20 Q. And how frequently were those reports
21 provided to the sales reps?

22 A. I don't know if they were provided any
23 more frequently than monthly, but I believe they were
24 given monthly reports. I don't know if any of those

1 reports were available in real time.

2 Q. Turning back actually to the page that
3 you're on right there, on the bottom right-hand corner
4 there's a reference to pharmacovigilance. Do you see
5 that?

6 A. Yes.

7 Q. What's your understanding of
8 pharmacovigilance?

9 A. Pharmacovigilance is the function or the
10 process of collecting information about -- real-world
11 information on the safety of a product or any other
12 quality issues or adverse events related to a product.

13 Q. And when you say adverse events, what are
14 you specifically referring to?

15 A. So in broad terms as defined by FDA, an
16 adverse event is any unwanted event that occurs while a
17 person is receiving treatment from a given drug.

18 Q. And what do you mean by unwanted event?

19 A. Unwanted event would be anything that's
20 unusual for that person in terms of their health and
21 which isn't the intended effect from the drug.

22 Q. And did Mallinckrodt perform -- or strike
23 that. Did Mallinckrodt track adverse event reports?

24 A. Yes, Mallinckrodt collected adverse event

1 information through our pharmacovigilance team and
2 reported that information to FDA.

3 Q. And can you give the court a general
4 understanding of how large the pharmacovigilance team
5 was at Mallinckrodt?

6 A. I don't know for sure how large the
7 pharmacovigilance team was specifically, but somewhere
8 on the order of five to 10 people is my understanding.

9 Q. And was that true for the entire time
10 period in which Mall -- from -- between when
11 Mallinckrodt first started manufacturing drugs --
12 opioids to present?

13 A. So I would say that initially when we
14 first began manufacturing generic opioids and when our
15 product line was smaller, we probably had fewer people.
16 I know we currently have fewer people than five, but
17 during the time when we marketed the branded opioids, I
18 believe we had a larger team.

19 Q. And is the pharmacovigilance group
20 associated with the medical affairs group at all?

21 A. It is a related function. At times it has
22 been part of medical affairs, yes.

23 Q. And what times were those?

24 A. During the time periods when we had

1 branded products it was part of medical affairs. Prior
2 to having branded products, we didn't have a formal
3 medical affairs group, and currently we no longer have
4 a medical affairs group related to the opioid products.

5 Q. So is it fair to say that the medical
6 affairs group at Mallinckrodt existed between the 2008
7 and 2015 time period only?

8 A. That I believe is generally true, but I
9 can't say that's the exact time frame.

10 Q. In other words, Mallinckrodt had a medical
11 affairs department during the times in which it
12 manufactured a branded opioid?

13 A. Yes, I believe that's correct.

14 Q. And with respect to the adverse event
15 reports, do you have any understanding of what database
16 they are contained in?

17 A. No, I don't know the specific database.

18 Q. And is it your understanding that
19 Mallinckrodt nevertheless maintained all adverse events
20 reports? Correct?

21 A. Yes.

22 Q. And how would Mallinckrodt obtain
23 knowledge of these adverse event reports?

24 A. So we're all trained as a company to

1 report anything that we receive from any channel, so
2 these could be reports where someone calls the
3 toll-free number that's on the bottle of product that
4 we sell. It could be a report that is referred by word
5 of mouth from a pharmacist to a sales representative
6 somehow, or it could be word of mouth that we as
7 individual employees hear.

8 But we also have as part of
9 pharmacovigilance a surveillance process where we look
10 at published literature, medical studies, other types
11 of reports to try to gather information that way.

12 Q. And again, all -- the people in the
13 pharmacovigilance were responsible for tracking all of
14 this; is that correct?

15 A. Yes, that's the group responsible for
16 tracking.

17 Q. And can you describe the general process
18 that Mallinckrodt undertook to elevate some of these
19 concerns more broadly across the business?

20 A. When we received information about adverse
21 events, there are defined rules for how to handle those
22 events. I am not prepared on the specifics of those
23 rules, but in certain cases certain activities are
24 required to be conducted which would require more broad

1 communication within the company and potentially even
2 notification of FDA. The adverse events information
3 was to my knowledge not generally reviewed within the
4 business but more within the medical affairs or
5 pharmacovigilance teams.

6 Q. And so you are sa -- if I understand you
7 correctly, there was a set protocol or a set of defined
8 rules which governed the process in which this
9 information was to be reviewed by either
10 pharmacovigilance or the medical affairs group?

11 A. Yes, we had approved company procedures on
12 how adverse events would be handled, tracked, reported.

13 Q. During the time that Mallinckrodt had a
14 medical affairs department, who was the head of the
15 medical affairs unit?

16 A. That person changed a couple of times. I
17 can't recall specific names.

18 Q. And approximately how large was the
19 medical affairs group?

20 A. Medical affairs in total I believe was
21 probably somewhere in the neighborhood of 10 people.

22 Q. And that's true for the two thousand --
23 roughly the 2008 through 2015 time period?

24 A. I believe so.

1 Q. Were they all in the St. Louis or the
2 Missouri office?

3 A. I can't say that for sure. We may have
4 had remote employees involved.

5 Q. Turn to the next page of that document. I
6 believe that should be Page 46.

7 A. Yes.

8 Q. You see that at least with respect to
9 Exalgo there appears to be an Exalgo safety advisory
10 board? Do you see that?

11 A. Yes.

12 Q. Do you know who determined who was going
13 to be on this board?

14 A. No, I do not.

15 Q. And the -- there's a reference to --
16 you'll see at the top left-hand corner of that box
17 there's a reference to Dr. Russell Portenoy. Do you
18 know who he is?

19 MR. TSAI: Object to the scope.

20 A. I have heard of Dr. Portenoy.

21 Q. (By Mr. Ko) And it appears that
22 Mallinckrodt had retained him to be on the safety
23 advisory board for Exalgo. Do you understand that to
24 be the case?

1 A. That appears correct from this document.

2 Q. Do you have any understanding of how long
3 he was on the safety advisory board for Exalgo?

4 A. No, I don't.

5 Q. I actually wanted to ask you a question
6 about deciles. We see that frequently in the
7 documents. Can you describe to the court how
8 Mallinckrodt utilized deciles in communication with its
9 marketing of branded opioids?

10 A. So we used deciles in order to identify
11 prescribers who we felt would be appropriate targets
12 for our marketing efforts for Exalgo and in order to
13 help in setting territories for the sales
14 representatives.

15 Q. And I believe I've seen references to the
16 documents of deciles between one and 10. Is that your
17 understanding of what the deciles were as designated by
18 Mallinckrodt?

19 A. Yes, deciles are numbered from one to 10.

20 Q. And can you describe to the court
21 generally speaking what that range represents?

22 A. So it represents, depending on -- it
23 represents something different depending on what is
24 being analyzed, but it's generally groupings of

1 physicians based upon the number of prescriptions that
2 they write for whatever drugs are defined in the
3 analysis.

4 Q. And is it fair to say that the higher the
5 decile, the higher the propensity of that doctor to
6 prescribe a certain drug?

7 A. Generally the higher deciles are for those
8 prescribers that prescribe the designated drugs more
9 often.

10 Q. And was there a general strategy at
11 Mallinckrodt with respect to its branded opioid
12 products to target doctors in the higher deciles?

13 A. So with a product like Exalgo, Exalgo is a
14 strong opioid that's designated for a very specific
15 patient set, and it is targeted towards patients who
16 are on established opioid therapy. Patients who are on
17 established opioid therapy are generally seen by
18 physicians who understand how to use opioids and who
19 understand the prescribing of strong opioids and the
20 risks associated.

21 In order to identify the physicians who
22 were likely prescribing the types of opioids, similar
23 to Exalgo where we felt that they would have patients
24 who were appropriate for Exalgo, we classify doctors

1 into deciles and looked at the higher deciles based
2 upon the definition we put in place to identify those
3 who are probably the best targets for Exalgo.

4 Q. So with respect to Exalgo, was the
5 strategy at Mallinckrodt to target doctors in the
6 higher deciles?

7 A. The strategy at Mallinckrodt was to target
8 prescribers who had an established history with
9 prescribing strong opioids and who had prescribing
10 patterns which indicated they understood how to use
11 those drugs.

12 Q. And earlier you were talking about an
13 established opioid therapy plan or established opioid
14 therapy provided by a physician. What is your
15 definition of an established opioid therapy plan?

16 A. Exalgo is meant to be used by patients who
17 are not opioid naïve, which means they are currently
18 receiving opioid therapy and their bodies are tolerant
19 of opioids to a certain level. It's a very strong
20 opioid and has to be used carefully, and physicians who
21 have little experience with prescribing opioids would
22 not be appropriate targets for our sales efforts.

23 Q. And when you say strong opioid, I
24 understand that Exalgo was offered in a 32-milligram

1 tablet. There were other milligram tablets of Exalgo;
2 is that correct?

3 A. Yes, that's correct.

4 Q. And what was the general range?

5 A. I believe it was eight to 32 milligrams.

6 Q. And over time was it the case that the
7 milligram amounts went up throughout the duration of
8 the Exalgo -- throughout the duration of Mallinckrodt's
9 manufacture and sale of Exalgo?

10 A. I'm not aware that we tracked the trends
11 in the prescribing of milligrams.

12 Q. Let me ask it a different way. Was --
13 when Exalgo first hit the market in 2008-2009, did
14 Mallinckrodt offer it in a 32-milligram form?

15 A. We developed the 32-milligram form later
16 after the initial launch because feedback from
17 prescribers and the data that we had in the market
18 suggested that there was a certain portion of
19 prescribers who had patients who needed a stronger dose
20 and who were dosing two 16-milligram tablets a day. In
21 order to ease the pill burden on patients and give
22 prescribers another option, we developed a 32-milligram
23 dose.

24 Q. So initially when Exalgo first hit the

1 market, the highest dosage it was provided in was a
2 16-milligram tablet or capsule?

3 A. The highest dose tablet that it
4 was provided in was 16 milligrams, but it was labeled
5 to be dosed to the appropriate level based upon the
6 decision of the prescriber.

7 Q. And the appropriate level was up to 32
8 milligrams, or was it some other amount?

9 A. There was not a limit set in the labeling.

10 Q. By the way, just for the record, this --
11 on this Page 46 that we're looking at, there's a
12 reference to HCPs. Is that in reference to health care
13 practitioners?

14 A. Health care practitioners. Correct.

15 Q. So synonymous with the physicians that
16 we're -- that are prescribing that we're talking about?

17 A. HCPs is a broader term to encompass
18 physicians, physician's assistants, nurse
19 practitioners, others who have prescribing ability.

20 Q. Fair enough --

21 A. So that's what we use.

22 Q. -- and thank you for that clarification.

23 And here it appears, at least based on the data that
24 Mallinckrodt has collected, there are approximately

1 18,000 HCPs in Deciles 5 through 10 and 47,000 HCPs in
2 Deciles 3 through 4?

3 A. Yes, that's --

4 Q. And is this based on survey data or is
5 this the IMS -- is this based on IMS data? Or what is
6 this based on?

7 A. This would be based on an analysis of IMS
8 data looking at a defined set of products.

9 Q. Are you familiar with the concept and term
10 chronic pain?

11 A. Yes.

12 Q. Was it generally the case that Exalgo was
13 marketed to individuals who were suffering from --
14 primarily suffering from chronic pain?

15 MR. TSAI: Object to form. Go ahead.

16 A. Exalgo was marketed to physicians and
17 other health care practitioners who treated patients
18 who had chronic pain. It was marketed to them for the
19 purposes of giving them another option to use with
20 patients who were appropriate for this type of therapy.

21 Q. (By Mr. Ko) Let me ask it a different
22 way. Do you understand the distinction between chronic
23 pain and acute pain?

24 A. Yes.

1 Q. And what's your understanding of that
2 distinction?

3 A. Chronic pain is a condition that -- where
4 pain has persisted and is expected to persist for a
5 long period of time. Acute pain is typically due to an
6 acute injury or a condition that will resolve in a
7 shorter period of time.

8 Q. And with respect to your answer in which
9 you said long period of time, what's your understanding
10 of that period? Do you have a -- do you or
11 Mallinckrodt have an understanding of what -- of how
12 long that time period is?

13 A. There's no official definition for what
14 that time period is. It's up to the health care
15 practitioner to decide if the patient that they are
16 treating has a condition which qualifies as a long
17 period of time or is a chronic condition and where they
18 think a long-acting product like Exalgo would be
19 appropriate.

20 Q. And when you say that it's up to the
21 health care practitioner to decide, what sort of
22 guidance did Mallinckrodt provide to that practitioner
23 either in the form of sales aids or otherwise to make
24 that determination?

1 A. Mallinckrodt sales aids and sales
2 communications provided information relative to the
3 dosing frequency, relative to labeled information
4 around how to convert patients from another opioid to
5 Exalgo, and other information about the warnings and
6 the risks of a product as strong as Exalgo, so that
7 those health care practitioners could use that
8 information along with their medical knowledge to make
9 the decision.

10 Q. And going back to the distinction between
11 acute pain and chronic pain, at least as you understand
12 it, is it fair to say that Exalgo was primarily
13 intended for patients with chronic pain?

14 A. Exalgo is labeled for patients who need
15 pain medication over an extended period of time, and we
16 targeted our selling efforts to physicians who we
17 believe treated patients with chronic pain.

18 Q. And in other words, Mallinckrodt did not
19 target physicians or did not otherwise market Exalgo
20 for acute pain treatment; correct?

21 A. We did not market Exalgo for acute pain.

22 Q. Conversely, Xartemis, however long its
23 shelf life was -- very brief -- that was marketed for
24 acute pain; correct?

1 A. That's correct.

2 Q. And as we discussed earlier, was extended
3 release; is that correct?

4 A. Also correct.

5 Q. And what was the highest dosage of
6 Xartemis?

7 A. Xartemis was available in one dose,
8 seven-and-a-half milligrams of oxycodone and 325
9 milligrams of acetaminophen labeled to be dosed every
10 12 hours.

11 Q. And during the short shelf life of
12 Xartemis in 2014, was that the only dosage amount that
13 Mallinckrodt offered?

14 A. Yes. That's correct.

15 Q. And Xartemis -- you originally --
16 Mallinckrodt originally sought approval from the FDA
17 for Xartemis as an abuse deterrent formulation; is that
18 correct?

19 A. That's correct.

20 Q. And what's your understanding of abuse
21 deterrent formulation?

22 A. Abuse deterrence as defined by FDA is --
23 are products with physical or chemical features
24 designed to either make abuse of the product more

1 difficult or less desirable.

2 Q. And which -- what type of features are we
3 talking about? What are -- can you get into the
4 specifics?

5 A. So I can't get into the specifics for
6 Xartemis, but in general these would be types of
7 features that would make it more difficult to
8 manipulate a product into a more abusable form.

9 Q. And is the reason that you can't get into
10 the specifics for Xartemis because you weren't prepared
11 for that --

12 A. Yes.

13 Q. -- to speak on that topic today?

14 A. Yes.

15 Q. But you do know that Xartemis applied for,
16 as we discussed, but did not receive FDA approval as an
17 abuse deterrent formulation; correct?

18 A. Yes, I'm aware of that.

19 Q. But Mallinckrodt still marketed Xartemis
20 as having abuse deterrent properties; correct?

21 MR. TSAI: Object to form.

22 A. We marketed Xartemis based upon its
23 physical features. We did not market Xartemis in terms
24 of having any proven abuse deterrent capabilities.

1 Q. (By Mr. Ko) Were there any materials that
2 you reviewed in preparation for this deposition today
3 in which you saw Xartemis as having abuse deterrent
4 properties?

5 A. No, I don't recall any materials that
6 referred to that.

7 Q. Going back to Exalgo, was there ever a
8 moment or was there ever a time in which Mallinckrodt
9 wanted to make Exalgo an abuse deterrent
10 formulation-type drug?

11 A. It is my understanding that we studied
12 Exalgo for abuse deterrent properties.

13 Q. And like Xartemis, did you apply to the
14 FDA for ADF approval for Exalgo?

15 A. I don't know if we did or not. I did not
16 prepare for that particular detail.

17 Q. And who other than the branded side of the
18 business would know the specific properties of Exalgo
19 and Xartemis?

20 A. What do you mean by specific properties?

21 Q. Well, let's take the abuse deterrent
22 properties, for example, or the application to the FDA
23 for abuse deterrent formulation status. Who was
24 responsible for making that application?

1 A. The regulatory affairs team would have
2 been responsible for making the application to FDA.

3 Q. Did the medical affairs department have
4 any input into that application process?

5 A. I don't know if medical affairs has any
6 input into the regulatory applications.

7 Q. And who was the head of the regulatory
8 affairs team during the 2009 through 2015 time period?

9 A. Again, it changed during that time period.
10 I can't recall the name of the person in charge of the
11 branded efforts.

12 Q. And approximately how large was the
13 regulatory affairs team during the 2009 through 2015
14 time period?

15 A. Between branded and generic products --
16 and those organizations would have also had
17 responsibility for our active ingredients business --
18 over time that group was as many as I think 20 or 25
19 people.

20 Q. And can you give the court a breakdown of
21 who may have been responsible for branded products
22 relative to generic products, or was such a distinction
23 made in that group?

24 A. That distinction was made, but it did

1 change fairly regularly, and I am not personally aware
2 of or don't personally recall who the brand leadership
3 was.

4 Q. And with respect to the generic aspect of
5 the regulatory affair team or regulatory affairs team,
6 what was their primary responsibility?

7 A. Regulatory affairs is primarily
8 responsible again for communicating with FDA on
9 product-related documents to be supplied to FDA, filing
10 applications for approval of generics, corresponding
11 with the agency.

12 Q. And how frequently did the regulatory
13 affairs team have to correspond with the FDA on generic
14 products of Mallinckrodt?

15 MR. TSAI: Objection to scope. Go ahead.

16 A. Frequently, regularly. I don't know for
17 sure, but there was frequent communication.

18 Q. (By Mr. Ko) Was it any different for the
19 branded aspect of the regulatory affairs team?

20 MR. TSAI: Objection to scope.

21 A. I don't believe it was any different on a
22 per-product basis. There were fewer branded products,
23 so the communication was probably less.

24 Q. (By Mr. Ko) And I know I asked you about

1 the head of the regulatory affairs department, but can
2 you recall any of the individuals who were higher up on
3 the regulatory affairs team in the 2009 through 2015
4 time period?

5 A. So senior director of regulatory affairs
6 at that time or at least during part of that time was
7 Diane Servello. She's no longer with the company.
8 Towards the end of her tenure I know she had
9 specifically generics responsibility. Earlier in her
10 tenure she may have at least for part of that time had
11 brand responsibility as well.

12 Q. So would you say that she had a lot of
13 responsibility with respect to communications made
14 between Mallinckrodt and the FDA?

15 MR. TSAI: Object to scope.

16 A. She would have been responsible for a
17 certain set of communications with FDA relative to
18 anything that had to do with our drug applications and
19 associated reports.

20 Q. (By Mr. Ko) And when you say certain set,
21 what do you mean?

22 A. Certain communication was filed directly
23 with FDA by other teams and wouldn't necessarily have
24 gone through Ms. Servello. Labeling information would

1 have been submitted directly by the labeling
2 department. The adverse event reports would have come
3 from the pharmacovigilance team.

4 Q. And would the pharmacovigilance team or
5 the labeling team interact with the regulatory affairs
6 team at all in connection with communications with the
7 FDA?

8 A. There may have been a internal
9 communication or approval process. I'm not sure of all
10 the specifics.

11 Q. And in addition to Diane --

12 A. Servello.

13 Q. -- Servello, do you recall any other
14 individuals with responsibility for communicating with
15 the FDA?

16 MR. TSAI: Object to scope.

17 A. Yes. More recently on the generic side,
18 our head of regulatory affairs is a gentleman by the
19 name of Donatus Ako-Arrey. In the past we have had a
20 number of different leaders of that group. I can't
21 recall all the names.

22 Q. (By Mr. Ko) And how long has that
23 individual been the head of regulatory affairs?

24 A. About two years.

1 MR. KO: And just to address Mr. Tsai's
2 objection to scope, I will note that Topic 31 indicates
3 that Mr. Vorderstrasse is here today to testify as to
4 statements made by Mallinckrodt to the FDA.

5 Q. (By Mr. Ko) In the -- as far as the
6 labeling department goes, who was in charge of the
7 labeling department from the 2009 through 2015 time
8 period?

9 A. I am not aware of who was in charge of
10 that department.

11 Q. Do you recall any names of people who had
12 responsibility with respect to labeling during that
13 time period?

14 A. The one name I recall was Howard Tweet.

15 Q. And what was his primary responsibility?

16 A. He was a manager within labeling. I don't
17 know the specific scope of his responsibilities.

18 Q. By the way, during the 2009 through 2015
19 time period when -- you were working in the generics
20 division; correct?

21 A. 2009 to 2011 I was in the corporate
22 strategy team, and then subsequent to 2011 was in
23 generics.

24 Q. And during the 2011 through two

1 thousand -- or from 2011 through present, have you had
2 interactions with the regulatory affairs group?

3 A. Yes.

4 Q. What are the nature of those interactions?

5 A. So in product management, we review and
6 approve certain documents. We review and approve the
7 physical product labels that go on packages. We are
8 involved in other sorts of discussions about the timing
9 relative to potential approval of new products or
10 changes of existing products.

11 Q. Going back to the discussion we were
12 having with respect to ADF -- these deterrent
13 formulations -- why did Mallinckrodt decide to enter
14 into that space?

15 MR. TSAI: Object to the form.

16 A. So Mallinckrodt evaluated and pursued
17 abuse deterrents in response to a number of factors,
18 including a general sense that industry health care
19 providers were interested in that technology and
20 interested in those types of products, as well as
21 statements from FDA about their interest in
22 manufacturers developing those technologies.

23 Q. (By Mr. Ko) And when would you say that
24 Mallinckrodt first started considered entering the ADF

1 space?

2 A. To my knowledge that was somewhere in the
3 2007 to 2009 time frame.

4 Q. And as we discussed before, Exalgo never
5 obtained ADF status, but there was a decision to try
6 and push Exalgo as an ADF-type opioid at some point in
7 time; is that correct?

8 A. No, there --

9 MR. TSAI: Object to form. Go ahead.

10 A. There was a decision to evaluate Exalgo
11 for abuse deterrent properties.

12 Q. (By Mr. Ko) That's -- fair enough. And
13 when was that -- approximately when was that evaluation
14 undertaken?

15 A. I don't know the exact time period. It
16 was early on in the Exalgo life cycle.

17 Q. Sometime after 2009?

18 A. Correct. Sometime around that time.
19 2010.

20 Q. And with respect to Xartemis, when did
21 Mallinckrodt first start evaluating Xartemis for
22 application of ADF status?

23 A. I believe we did the abuse deterrent
24 studies and evaluations of Xartemis prior to approval,

1 prior to the initial approval of the drug.

2 Q. And prior to the initial approval in 2014?

3 A. Correct.

4 Q. By the way, when specifically was Xartemis
5 approved?

6 A. I don't know the exact date. I do believe
7 it was in 2014.

8 Q. And as we discussed it had -- it was just
9 the one year in which Xartemis was manufactured and
10 sold by Mallinckrodt. When did it end, or when did
11 Mallinckrodt pull Xartemis from the market?

12 A. We actively promoted Xartemis for about a
13 year, and after that time we continued to sell very
14 small quantities to wholesalers until early 2015, so --
15 I believe it was early -- no, early 2016.

16 Q. So even though -- so when we talk about
17 Mallinckrodt pulling Xartemis off the market, there was
18 still nevertheless some small amount of sales to
19 distributors of Xartemis after that period of time?

20 A. After we stopped the promotion on the
21 branded side there was a bit of residual sales, yes.

22 Q. I see. Very minimal?

23 A. Correct.

24 Q. And why did Mallinckrodt decide to pull

1 Xartemis so quickly?

2 A. It became quickly apparent that the market
3 was not accepting the product, didn't see the
4 advantages, and we weren't able to significantly grow
5 prescriptions.

6 Q. And with respect to Exalgo -- Mallinckrodt
7 stopped promoting Exalgo, as you said, sometime around
8 2015 -- was there also a period of time in which it had
9 residual sales after it stopped marketing Exalgo?

10 A. Yes. Exalgo -- we ceased marketing of
11 Exalgo when generics for Exalgo launched and Exalgo as
12 a branded product -- we continued to sell it as a
13 branded product without any promotion until very
14 recently, and we also sold a generic version as well
15 during the time after we ceased promotion of the brand.

16 Q. And so when did Mallinckrodt begin selling
17 the generic version of Exalgo?

18 A. In the 2014 time frame.

19 Q. And it continues to sell the generic form
20 today; correct?

21 A. As of today, yes.

22 Q. And what -- approximately what percentage
23 of its overall generic portfolio does the Exalgo
24 generic represent?

1 A. Exalgo generic represents very little.
2 Probably one percent of our portfolio.

3 Q. In terms of the current generic portfolio,
4 what are the primary generic opioids that represent
5 Mallinckrodt's generic portfolio? Strike that. Today,
6 what generic opioids represent the largest proportion
7 of Mallinckrodt generic opioids?

8 A. So our largest generic product today in
9 terms of volume and dollars is hydrocodone with
10 acetaminophen tablets followed I believe by
11 oxycodone with acetaminophen tablets.

12 Q. And for the hydrocodone with
13 acetaminophen -- I've also seen it referred to as APAP
14 in the documents.

15 A. Correct.

16 Q. So for that, what percentage of the
17 overall portfolio does that represent?

18 A. That -- I believe that product represents
19 roughly 10 percent of the dollars of our entire generic
20 sales and probably represents half of the unit volume.

21 Q. And the unit volume being the --

22 A. Meaning individual tablets sold.

23 Q. Right. I was just about to say we
24 discussed earlier today your definition of units as

1 being individual tablets?

2 A. Yeah, that's correct for this case.

3 Q. And then same question with respect to the
4 oxycodone with acetaminophen. What percentage in terms
5 of dollars does that represent relative to the overall
6 generic portfolio today?

7 A. Generally I believe that's -- that
8 product's roughly 10 to 15 percent of our total generic
9 sales and probably 20 percent of our unit volume.

10 Q. Got it. So between the two, sounds like
11 by unit volume they represent about 70 percent of the
12 overall generic portfolio?

13 A. I believe that's correct.

14 Q. And anywhere from 20 to 25 percent in
15 terms of sales in dollars?

16 A. That's correct.

17 Q. Are you aware of any studies or research
18 talking about the primary ways in which opioids are
19 abused and misused?

20 A. I am generally aware that those topics
21 have been studied by various different medical
22 professionals. I'm not specifically aware of any
23 studies.

24 Q. And if I told you that there were some

1 studies that were performed that -- assuming I can
2 prove at trial that there were studies that establish
3 that the primary way in which opioids are abused are
4 through ingestion -- and by primary I mean over 50
5 percent -- to what extent does an ADF opioid address
6 that concern?

7 MR. TSAI: Object to the form of the
8 question.

9 A. So first of all, it's a hypothetical
10 question --

11 Q. (By Mr. Ko) Sure.

12 A. -- so I don't know how to evaluate that.
13 But ADF is a broad definition which changes as
14 available technology changes. If a company was able to
15 develop an abuse deterrent formulation technology which
16 provided some level of resistance to oral abuse, that
17 would be -- obviously that would help provide that type
18 of deterrent.

19 Q. Are you aware of any type of abuse
20 deterrent formulation technology which provides some
21 level of resistance to oral abuse?

22 A. I am aware that there are companies who
23 are working to develop such technology, but there are
24 no currently approved products that incorporate

1 something like that.

2 Q. Did Mallinckrodt ever develop such
3 technology?

4 A. Not to my knowledge.

5 Q. Are you familiar with the concept that
6 Mallinckrodt marketed some of its branded opioids as --
7 well, Xartemis in particular as having less peaks and
8 valleys with respect to the onset of pain?

9 A. I know that we communicated information
10 about the pharmacokinetic profile which showed a more
11 level blood levels of drug as compared to immediate
12 release products.

13 Q. How about within the extended release
14 world? Was there anything about Xartemis in terms of
15 peaks and valleys that were different than the other
16 extended release drugs on the market?

17 MR. TSAI: Object to form.

18 A. Xartemis was unique in that it was the
19 only extended release oxycodone with acetaminophen
20 combination product, so there was really no other
21 extended release product to compare to.

22 Q. (By Mr. Ko) With respect to the -- were
23 there representations made in the marketing materials
24 on Xartemis about that particular drug having fewer

1 peaks and valleys regarding pain than other branded
2 opioid drugs on the market?

3 A. I am not aware that the marketing
4 statements made such claims relative to peaks and
5 valleys of pain.

6 Q. Jumping back to the generic opioids that
7 Mallinckrodt manufactured, we talked earlier today
8 about oxy 15s and oxy 30s. Do you recall that?

9 A. Yes.

10 Q. And Mallinckrodt still continues to
11 manufacture and sell those products; is that correct?

12 A. That is correct.

13 Q. And have you ever heard of the term roxies
14 or blues?

15 A. I believe I've heard of the term roxies.

16 Q. You've never heard of the term blues?

17 A. I don't think I have.

18 Q. Have you ever heard of the term M's?

19 A. No.

20 Q. And so your understanding of roxies --
21 what's your understanding of that term?

22 A. My understanding is that's a street name
23 for Roxicodone.

24 Q. And what -- Roxicodone and what dosage?

1 A. That I don't know.

2 Q. And is Roxicodone a generic version of
3 oxycodone?

4 A. Roxicodone is a brand-name version of
5 oxycodone that --

6 Q. That Mallinckrodt manufactured?

7 A. Mallinckrodt does manufacture Roxicodone
8 and we do sell very small volumes of that product.

9 Q. Didn't Mall -- just let me make sure I get
10 this straight. You said Roxicodone is a branded opioid
11 product; correct?

12 A. It is a brand-name product that we have
13 never marketed or promoted with a sales force of any
14 kind.

15 Q. But Roxicodone has a generic form as well;
16 correct?

17 A. That's correct.

18 Q. And Mallinckrodt manufactures and sells
19 that generic form; correct?

20 A. That's correct.

21 Q. And Mallinckrodt manufactured and sold the
22 generic version of Roxicodone from approximately what
23 time period or during what approximate time period?

24 A. Approximately the late 1990s through

1 today.

2 Q. And what -- we were talking about general
3 market share of the generic portfolio today of the
4 oxycodone APAP and the hydrocodone APAP. What
5 percentage does Roxicodone represent of the overall
6 generic portfolio of Mallinckrodt?

7 A. Are you referring to specifically to the
8 branded Roxicodone?

9 Q. I'm referring specifically to the generic.

10 A. Generic Roxicodone. Generic Roxicodone
11 immediate release tablets, probably on the order of 10
12 percent of our total portfolio.

13 Q. And during the 2007 through 2010 time
14 period, approximately what percentage did Roxicodone,
15 the generic version, represent of Mallinckrodt's
16 overall generic portfolio?

17 A. I don't know offhand the specifics. I
18 believe it was a slightly larger percentage than it is
19 today because we had fewer products in our portfolio
20 then.

21 Q. Are you aware at all or have you seen any
22 information about the abuse and misuse of generic
23 roxies at any time?

24 A. I am aware that there is abuse of generic

1 oxycodone products.

2 Q. And are you aware that there is specific
3 abuse of generic Roxicodone that Mallinckrodt
4 manufactured?

5 A. I'm not personally aware of specific cases
6 of abuse of Mallinckrodt Roxicodone, but I know that in
7 general generic versions of oxycodone are abused.

8 Q. And when we were talking earlier about
9 adverse events reports, I just want to be sure I
10 understand who may know the most about abuse of generic
11 Roxicodone that Mallinckrodt manufactured. Which
12 department would most likely be aware of this
13 information, if any?

14 A. Well, the pharmacovigilance team would
15 capture and track that information.

16 Q. Would --

17 A. -- as it's reported to us.

18 Q. Sorry. I didn't mean to interrupt. Do
19 you know whether or not Karen Harper or Bill Ratliff
20 had any interactions with the pharmacovigilance
21 department?

22 A. I don't know if they have or not.

23 Q. Do you know whether or not DEA compliance
24 groups or departments at Mallinckrodt would interact

1 with the pharmacovigilance team?

2 A. Yeah, I'm not aware if they do or not.

3 MR. KO: Why don't we take a quick break?

4 I think we've been going for a little over an hour.

5 THE VIDEOGRAPHER: We are going off the
6 record at 4:03 PM.

7 [A brief recess was taken.]

8 THE VIDEOGRAPHER: We are back on the
9 record at 4:18 PM.

10 Q. (By Mr. Ko) Okay, Kevin. Thank you for
11 your patience today. I just have a few more questions
12 or a series of questions and then I will be done.

13 A. Okay.

14 Q. So thank you for your time. The court
15 reporter has handed you a copy of what has been marked
16 as Exhibit KV 16.

17 [Exhibit Mallinckrodt-Vorderstrasse-016
18 marked for identification.]

19 Q. And for the record, KV 16 is Bates-labeled
20 MNK-T1_0000855019, and it's an e-mail dated May 7th,
21 2013, and it contains an attachment titled Exalgo
22 marketing programs ROI. Do you see that, Kevin?

23 A. I do.

24 Q. And we can turn to the e-mail for

1 reference if you need to, but I mostly have questions
2 on the attachment. Do you recognize this document at
3 all?

4 A. No, I do not.

5 Q. Earlier we had talked about your general
6 skill set including strategies with respect to return
7 on investment, and this appears to be a document that
8 is talking about Exalgo marketing -- the return on
9 investment of Exalgo marketing programs. Is that fair?

10 A. That is how they are titled, yes.

11 Q. And generally speaking, can you describe
12 to the court why it was important for Mallinckrodt to
13 perform ROI-type analysis with respect to its opioid
14 products?

15 A. Well, I'm not familiar with these
16 documents.

17 Q. And actually, I have a few specific
18 questions on this document potentially, but I should
19 have just asked you directly.

20 A. Uh-huh.

21 Q. So let me ask you directly. Why was it
22 important for Mallinckrodt to engage in ROI-type
23 analysis with respect to its opioid products?

24 A. In general a business would engage in an

1 ROI analysis to understand if their investments, if
2 their spend is achieving the results that they have
3 expected up front. Since I'm not familiar with this
4 particular analysis, I don't know why it was conducted
5 yet, but understanding that -- the purpose of an ROI
6 analysis is to determine if the plan that you've put in
7 place is delivering the results you expect.

8 Q. And to the best of your knowledge did
9 Mallinckrodt perform RO-type analyses with respect to
10 Magnacet, TussiCaps, Exalgo, and Xartemis?

11 MR. TSAI: Object to the form.

12 A. To the best of my knowledge we did not
13 routinely perform ROI analysis on any of our branded
14 products.

15 Q. (By Mr. Ko) And what is your definition
16 of routinely perform?

17 A. As a part of regular and recurring
18 business activities.

19 Q. Did you perform any type of ROA analys --
20 ROI analysis in connection with your generic portfolio?

21 A. I do not recall any ROI analysis of our
22 marketing efforts within generics.

23 Q. And separate and apart from marketing
24 efforts, was there any kind of ROI-type analysis done

1 on any aspect of the generic line of Mallinckrodt's
2 business?

3 A. We did do ROI analysis on capital
4 investment decisions to try to prospectively identify
5 if a particular investment would have a financial
6 benefit. We may have conducted other ad hoc analyses
7 which were ROI-type analyses on other activities.

8 Q. And for the former that you just
9 described, what was the baseline or denominator, for
10 lack of a better term, on that analysis of capital
11 investments? In other words, what -- how were you
12 measuring your return on investment with respect to
13 capital investments?

14 A. In general, capital investment decisions
15 are analyzed based upon the assessment of what the
16 incremental capability would be that we're putting in
17 place with the additional capital and a comparison of
18 that incremental revenue and profit benefit to the
19 actual cost of that capital.

20 Q. And so when we're talking about capital
21 investments, is it fair to say that your capital
22 investment decisions as it relates to the generic side
23 of Mallinckrodt's business -- were these analyses done
24 in connection with acquiring a specific generic

1 portfolio or product, or provide -- or can you provide
2 the context of what capital investments you're talking
3 about?

4 A. So the type of capital investment analysis
5 I'm talking about would have been relative to
6 installation of new equipment or changes at the
7 manufacturing facility which would be needed to
8 increase capacity, for instance.

9 Q. Going back to this document, the cover
10 e-mail, it appears that there's an e-mail exchange --
11 at least the top e-mail between Melissa Falcone and
12 Michael Wessler. Do you see that?

13 A. Yes.

14 Q. Who's Michael Wessler?

15 A. Michael Wessler was a -- either a product
16 manager or a marketing manager within the branded team.

17 Q. And we talked earlier today about Melissa
18 Falcone, and you spoke with her in connection with
19 preparing for this deposition; correct?

20 A. That's correct.

21 Q. And it appears that she was a senior
22 product manager of Specialty Pharmaceuticals at
23 Mallinckrodt?

24 A. Yes.

1 Q. And remind me -- is that her current role
2 right now as well?

3 A. No, that is not her current role any
4 longer.

5 Q. What is her current role now?

6 A. I am not certain of her exact title, but
7 she is involved in market access for Mallinckrodt's
8 current -- some of Mallinckrodt's current branded
9 products.

10 Q. And did she have any involvement at any
11 time with respect to Mallinckrodt's generic portfolio?

12 A. No, she had no direct involvement with the
13 generics portfolio.

14 Q. And then going back to Exhibit 2, as we
15 discussed, you did speak with Ms. Falcone in connection
16 with preparing for this deposition. Approximately how
17 long did you speak with her?

18 A. I believe the conversation was less than
19 an hour.

20 Q. And what did you discuss?

21 MR. TSAI: Objection. As testified, an
22 attorney was present, so I instruct the witness not to
23 reveal the substance of any attorney-client privileged
24 communications.

1 Q. (By Mr. Ko) And did you -- are you going
2 to follow that instruction?

3 A. Yes.

4 Q. And did you ever speak with Ms. Falcone
5 outside of the presence of counsel?

6 A. Not in relation to this matter.

7 Q. Going back to Exhibit 2, I just want to
8 understand more some of the materials you reviewed, and
9 let's take Topic 10, for example. It indicates here
10 that you reviewed Mallinckrodt's amended responses to
11 plaintiff's second set of interrogatories. Do you see
12 that, on the far right-hand column?

13 A. Yes.

14 Q. Did you review any other court pleadings
15 or documents in connection with preparing for this
16 deposition today?

17 A. Not to my knowledge, no.

18 Q. Are you aware that -- well, you're aware
19 that there have been -- depending on how you count it,
20 but approximately 1,500 jurisdictions that have filed
21 suit in connection with the opioid crisis?

22 A. Yes, I'm generally aware.

23 Q. And do you understand that a lot of those
24 lawsuits include Mallinckrodt as a defendant?

1 A. Yes.

2 Q. Have you read any of those complaints that
3 allege Mallinckrodt is responsible or at fault for the
4 opioid crisis?

5 A. No, I have not.

6 Q. You've not read any -- you understand that
7 discovery in this case in particular is happening in
8 part for certain bellwether trials that are scheduled
9 to occur next September? Do you understand that?

10 A. Yes, I understand that.

11 Q. And do you know who those bellwethers are?

12 A. Not specifically, no.

13 Q. And do you understand that the bellwethers
14 are generally in northeast Ohio or include
15 jurisdictions in Ohio?

16 A. That I'm aware of, yes.

17 Q. And have you read the complaint that has
18 been filed by any of the bellwethers that will be going
19 to trial scheduled for next September?

20 A. No, I have not read the complaint.

21 Q. Why not?

22 MR. TSAI: Object to form.

23 A. Because I wasn't instructed that it was
24 necessary to read the complaint.

1 Q. (By Mr. Ko) Apart from being instructed,
2 were you curious at all about the allegations contained
3 in that complaint about why Mallinckrodt is responsible
4 for this crisis?

5 MR. TSAI: Object to form.

6 A. So in discussion with inside and outside
7 counsel --

8 MR. TSAI: Wait. Hold on. If you're
9 going to talk about discussions with counsel, I
10 instruct you not to answer.

11 A. Okay. Fair enough.

12 Q. (By Mr. Ko) Are you aware of any rulings
13 that have occurred in connection with the national
14 opioid litigation issued by either Judge Polster or
15 Special Master Cohen?

16 A. I'm not aware of specific rulings.

17 Q. Are you aware of a report and
18 recommendation issued by a magistrate judge in Ohio
19 regarding defendants' motions to dismiss?

20 MR. TSAI: Objection as to scope of this
21 line of questions. Go ahead.

22 A. I'm not sure if I know anything about
23 that, no.

24 Q. Sure. So just to confirm, you haven't

1 read any of the pleadings or orders that have been
2 issued in connection with the national opioid
3 litigation pending in Ohio; is that correct?

4 A. So I have read the notice of deposition
5 which contains the topics on which I've prepared, and I
6 have read excerpts from what I believe is the main
7 complaint.

8 Q. Oh, okay. So you have reviewed the
9 complaint?

10 A. I have not reviewed the complaint. I've
11 read small portions of it.

12 Q. And which portions did you review?

13 A. I don't know for sure. I had the
14 document. I glanced at it. So I've seen some of it.

15 Q. And do you know which complaint you
16 reviewed?

17 A. I don't know specifically what it was, no.

18 Q. Other than the amended notice that is
19 reflected in Exhibit 1 and excerpts of the complaint,
20 have you reviewed or read any other court pleadings
21 from the national opioid litigation?

22 A. No, I don't believe so.

23 MR. KO: All right. That's all I have for
24 you. Thank you so much for your time. Appreciate your

1 patience. Sadly, I think you're going to have more
2 questioning. I just do want to note I think we're
3 going to just try and transition without taking a
4 break.

5 MR. TSAI: Okay.

6 MR. KO: But just so we note for the
7 record pursuant to the deposition protocol in this
8 case, which allows plaintiffs to take 30(b)6 deposition
9 testimony, when Mallinckrodt designates more than one
10 witness to testify as to the topics in Exhibit 1, the
11 court has allowed for 14 hours of questioning, and
12 today we have gone for approximately five hours and 40
13 minutes, I believe, so plaintiffs -- we'll note for the
14 record that plaintiffs have approximately eight hours
15 and 20, 25 minutes for the remaining two witnesses as
16 designated by Mallinckrodt.

17 THE VIDEOGRAPHER: Do you want to go off
18 the record?

19 MR. KO: I think we can just go briefly
20 off the record so that we can switch --

21 THE VIDEOGRAPHER: We're going off the
22 record at 4:32 PM.

23 [Discussion off the record.]

24 THE VIDEOGRAPHER: We are back on the

1 record at 4:33 PM.

2 QUESTIONS BY MS. HERZFELD:

3 Q. Okay. Mr. -- it's "Vorderstrasse," as
4 you say it?

5 A. Yes.

6 Q. You don't say "strassa" in the German way?

7 A. I don't, no.

8 Q. Do other people say it that way?

9 A. Sometimes.

10 MS. HERZFELD: My name is Tricia Herzfeld
11 and I am one of the attorneys representing the
12 plaintiffs in the Tennessee state litigation. Before
13 we get started today, I just want to put a couple of
14 objections on the record. Number 1, I think my
15 objection to my time today being counted against the
16 MDL has already been stated, but I want to be very
17 clear that we've given plenty of sufficient notice to
18 Mallinckrodt about our intention to participate today,
19 in which we were invited by Mallinckrodt to participate
20 here, and it wasn't until 2:00 PM when the deposition
21 was already well underway that Mallinckrodt is for the
22 very first time raising this issue of having to share
23 time with the MDL, to which we of course object.

24 Secondly, as has been our ongoing

1 objection to the depositions that we've been
2 cross-noticed to in this case, we believe that
3 Mallinckrodt has not appropriately followed the
4 guidelines set down by the MDL court for the
5 cross-noticing of us in these depositions, for the
6 providing of documents, and ensuring that we have
7 sufficient information to go forward to question these
8 witnesses about Tennessee issues for depositions where
9 we have been cross-noticed. I'm sure counsel will want
10 to say something back as he always does, but those are
11 our objections.

12 MR. TSAI: Just for the record, we
13 disagree with these characterizations and I -- we heard
14 earlier today that state counsel stated that she had
15 not reviewed the MDL order and in fact is intending to
16 take a second 30(b)6 deposition of the company, which
17 violates the principle underlying the court's orders,
18 and with that we reserve all rights accordingly.

19 MS. HERZFELD: And I just want to be very
20 clear I didn't say I hadn't reviewed the MDL order. I
21 said I wasn't subject to the 14 hours. Our state
22 case is not part of the MDL. We're under our own
23 jurisdiction, as you are aware. We'll deal with that
24 in the state court issue, but we fully intend to take

1 our own 30(b)6, just to be clear.

2 MR. KO: And just so I'm not left out of
3 the party, I concur -- I concur in Tricia's general
4 objection that any time she takes today should not be
5 counted against the 14 hours that we have been provided
6 for pursuant to the clear terms of the MDL, and as
7 noted by Tricia we were not given notice until 2:00
8 today that Mallinckrodt was taking this position.

9 MS. HERZFELD: Okay. Moving on, because I
10 think we all have flights to make.

11 Q. (By Ms. Herzfeld) Mr. Vorderstrasse, did
12 you do anything specifically to prepare for questions
13 about Tennessee for your deposition today?

14 A. No, I did not.

15 Q. Did you discuss with anybody any
16 particular issues about Mallinckrodt's business in
17 Tennessee in preparation for your deposition today?

18 A. I discussed with my attorneys as part of
19 preparation the general concept of the issue relative
20 to Tennessee.

21 Q. And so you have been prepared to answer
22 questions about Tennessee for your testimony today?

23 A. I have been generally prepared to answer
24 some questions about Tennessee.

1 Q. And what is your understanding of the
2 state litigation in Tennessee?

3 A. Very minimal. I know that it has
4 something to do with drug trafficking laws, and that's
5 about the extent of it.

6 Q. And do you have any idea who the
7 plaintiffs are in the case?

8 A. Not specifically, no.

9 Q. What about generally?

10 A. I don't know whether it's the state itself
11 or if there are others.

12 Q. And what about drug trafficking laws do
13 you understand the lawsuit to be about?

14 A. I really don't. I just know that that's
15 generally what it's related to.

16 Q. And other than your attorneys, did you
17 speak with anybody else about any drug trafficking
18 issues, as you said, or Mallinckrodt's businesses in
19 Tennessee before your deposition today?

20 A. No.

21 Q. Did you review the complaint or any other
22 documents from the Tennessee litigation before
23 testifying today?

24 A. No.

1 Q. Have you seen any portion of it?

2 A. No.

3 Q. Has anybody summarized it for you?

4 A. No.

5 Q. Earlier today you were talking about
6 procedures related to compensation -- it's Topic 10
7 which you've been identified -- for folks that had
8 oversight or control over marketing, sales,
9 distribution of prescription opioids for the Case Track
10 1 jurisdictions. Do you remember that general
11 testimony from this morning?

12 A. Yes.

13 Q. And does that compensation scheme -- is
14 that different at all for Tennessee?

15 A. The compensation practices -- excuse me --
16 that we used for our branded sales representatives were
17 individualized, the territories were individualized
18 based upon sales representative, but the overall
19 compensation plan and the way it was built was
20 consistent throughout the country.

21 Q. And what sales region was Tennessee?

22 A. I don't know specifically how that region
23 was designated.

24 Q. Do you know anything about it changing

1 over time?

2 A. I don't know specifics about it changing
3 over time. I am aware that the sales territories were
4 reevaluated on a periodic annual basis.

5 Q. Have you ever heard somebody refer to a
6 sales territory called the Nashville district?

7 A. No, I don't think so.

8 Q. And who is responsible for dividing up the
9 various districts?

10 A. The sales districting plan was assembled,
11 analyzed by the commercial analytics team and was
12 subsequently approved by sales management.

13 MS. HERZFELD: And I'm going to hand you
14 what we're going to mark as Exhibit -- what number?

15 THE REPORTER: 17.

16 MS. HERZFELD: 17.

17 [Exhibit Mallinckrodt-Vorderstrasse-017
18 marked for identification.]

19 Q. (By Ms. Herzfeld) Have you had a chance
20 to take a look yet?

21 A. Not the entire document.

22 Q. Flip through. Take your time.

23 A. Okay.

24 Q. Okay. So I have just a couple questions.

1 I want to make sure I understand how you guys break
2 things down. So within Mallinckrodt in your sales
3 force you have -- what is it -- regions and then
4 districts and then territories, all kind of getting
5 smaller as they go along; is that right?

6 A. Yes, that's generally correct.

7 Q. And so when you look at the second slide
8 here, and what it is I've shown you, which appears to
9 be the sales force alignment and placement for MNK795
10 launch, map reports for north central region, dated
11 October 24th, 2013. Did I read that correctly?

12 A. Yes, you did.

13 Q. What is MNK795?

14 A. MNK795 was the research program identifier
15 for the product which became Xartemis XR upon approval.

16 Q. And was the map reports for the various
17 sales forces -- were those different for -- how do you
18 say it? "Xart-emis"?

19 A. "Xar-temis."

20 Q. "Xar-temis"? Than they were for
21 Mallinckrodt's other branded products, or were they
22 generally the same?

23 A. So I can't say for sure how these differ
24 from past district and territory alignments, but we

1 reevaluated the entire sales plan for the launch of
2 Xartemis, and as a result of that we drew specific
3 territories based upon our analysis of prescribers.

4 Q. And were you personally involved in that
5 process?

6 A. I was not.

7 Q. And which team would have been involved in
8 that?

9 A. This was formally known as the global
10 business insights and forecasting team, also referred
11 to as commercial analytics, which was a part of the
12 branded business group at that time.

13 Q. And what's it called now?

14 A. That group no longer exists.

15 Q. Oh, that's one that no longer exists?

16 Okay. Okay. And so at least in 2013 these were the
17 regions, the districts, and the territories for at
18 least a certain section of the country? That's what
19 we're looking at here; right?

20 A. Yes, that's correct.

21 Q. And so do you see if it says region north
22 central in the second slide on the first page?

23 A. Yes.

24 Q. Do you see the State of Tennessee included

1 in that?

2 A. I do.

3 Q. So would it appear from this document then
4 that the State of Tennessee was included in the north
5 central region?

6 A. Yes, I agree with that.

7 Q. Now, if you'll flip to the second page
8 with me.

9 A. And actually I should clarify.

10 Q. Yes, sir.

11 A. It looks like most of Tennessee is in
12 north central region. I don't know if the rest of
13 Tennessee was included elsewhere, just to --

14 Q. Well, that's actually a very astute point.
15 It looks like Memphis is not, so that's a very good
16 point and I take it. Flipping to the second page, it
17 says district Nashville, Tennessee. Do you see where
18 I'm looking at?

19 A. Uh-huh.

20 Q. The very first slide?

21 A. Yes.

22 Q. And so going from -- you probably don't
23 know where Jackson, Tennessee, is, do you? It's not on
24 the map.

1 A. Yeah.

2 Q. I'll submit to you that Jackson is about
3 halfway between Nashville and Memphis, so I'm going to
4 kind of draw this line where the end of the blue is
5 there and call it Jackson. Going from most of
6 Tennessee over to the east. Does it look like most of
7 Tennessee there is included within the district called
8 Nashville, Tennessee?

9 A. Yes, it appears so.

10 Q. And then the various territories are
11 included within that. If you keep flipping with me,
12 you've got a couple territories there in North
13 Carolina. If you flip to the next page, which is Page
14 4 of this exhibit, there is also a territory for
15 Knoxville, Tennessee, territory for Nashville,
16 Tennessee, territory for Chattanooga, Tennessee,
17 territory for Johnson City, Tennessee. Keep flipping.
18 And then you've got north and south Nashville,
19 Tennessee. Do you see all those?

20 A. Yes, I do.

21 Q. And those were all designated as separate
22 territories within the Nashville district; is that
23 correct?

24 A. Yes, that's correct.

1 Q. And did you have anything to do with those
2 designations?

3 A. No, I did not.

4 Q. And how many salespeople would cover each
5 territory?

6 A. It's my understanding that each territory
7 would have one sales representative.

8 Q. And would they sometimes have more than
9 one territory or did you generally do one per
10 territory?

11 A. My general understanding is it's one per
12 territory.

13 Q. And did you have anything to do with
14 receiving information from those salespeople from those
15 territories within Tennessee?

16 A. No, I did not personally.

17 Q. Did you oversee people who did?

18 A. No, I did not.

19 Q. So do you have any information about any
20 sales information that would have been coming from the
21 various territories in Tennessee making its way up
22 through the upper echelon of Mallinckrodt?

23 A. I do not have any of that information, no.

24 Q. Great. Do you know who would?

1 A. So that would be contained in our
2 financial records. In terms of individuals who might
3 have that information, I'm not sure any individuals who
4 would still be with the company who would have that
5 information.

6 Q. Can you think of any names of people who
7 are no longer with the company who might have that
8 information?

9 A. I'm trying to think if this is the time
10 period when Ron Wickline was in charge of the sales
11 team.

12 Q. Can you think of anybody else?

13 A. I guess Hugh O'Neill was the president of
14 pharmaceuticals at the time.

15 Q. Can you think of anybody else?

16 A. Not specific names, no.

17 Q. Have you ever been to Tennessee?

18 A. I have been to Tennessee, yes.

19 Q. Where have you been?

20 A. Nashville, Memphis, Chattanooga.

21 Q. And you just come as a visitor? Do you
22 own property?

23 A. Just a visitor.

24 Q. And when's the last time you've been to

1 Tennessee?

2 A. I guess October.

3 Q. October of this year?

4 A. Yes.

5 Q. Oh, okay. Where did you go?

6 A. I drove through.

7 Q. Have you ever been to upper east

8 Tennessee, Appalachian region?

9 A. I've driven through that area.

10 Q. What years?

11 MR. TSAI: Objection to scope.

12 Q. (By Ms. Herzfeld) You can answer.

13 A. Gosh, I guess it was probably 1995 or

14 1996.

15 Q. Have you ever been to Tennessee for work?

16 A. Yes.

17 Q. And when would that have been?

18 A. Approximately three -- three or four years

19 ago to the Memphis area.

20 Q. Was that the only time for work that

21 you've come to Tennessee?

22 A. I think I attended a conference there back

23 in the 1990s.

24 Q. Other than the conference and the time

1 going to Memphis?

2 A. That was the only two times.

3 Q. And what brought you to Memphis three or
4 four years ago for work?

5 MR. TSAI: Objection to scope. What topic
6 does this relate to? What 30(b)6 topic does this
7 relate to?

8 Q. (By Ms. Herzfeld) You can answer the
9 question.

10 A. I came to Memphis to visit two customers
11 in the generics business at that time.

12 Q. And who were the two customers?

13 A. McKesson was one, and AcelRx. They were a
14 hospice provider.

15 Q. And what brought you to visit those two
16 customers in Memphis?

17 A. Just a general business discussion and
18 just a relationship meeting.

19 Q. Who asked for the meeting -- them or you?

20 MR. TSAI: Objection to scope.

21 A. I don't recall.

22 Q. (By Ms. Herzfeld) And were either of
23 those customers folks that distributed Mallinckrodt's
24 opioid products?

1 A. McKesson distributed our opioid products
2 and AcelRx purchased our opioid products for dispensing
3 to their pharmacy patients.

4 Q. And were Mallinckrodt's opioid products
5 discussed at all during those two meetings?

6 MR. TSAI: Object to scope.

7 A. I believe so.

8 Q. (By Ms. Herzfeld) What was the content of
9 those discussions?

10 MR. TSAI: Object to scope.

11 A. I don't recall the content.

12 Q. (By Ms. Herzfeld) Were you selling?

13 A. Those were not sales calls. Those were
14 general relationship calls where we visited their
15 facilities to see their operation, and I'm sure in the
16 course of that visit we saw our product in their
17 distribution centers and discussed general comments
18 about how our products were either used or transported.

19 Q. And were there -- was there any discussion
20 about diversion of Mallinckrodt opioids at either of
21 those meetings?

22 MR. TSAI: Object to scope. Diversion is
23 outside the scope of the designated topics for this
24 witness.

1 A. I don't recall any such discussions.

2 Q. (By Ms. Herzfeld) What about the abuse of
3 Mallinckrodt opioids or opioids in general at those
4 meetings?

5 A. I don't recall anything like that.

6 Q. Is there anything else about the
7 discussions that you do recall?

8 MR. TSAI: Object to scope. Not a proper
9 30(b)6 topic.

10 Q. (By Ms. Herzfeld) You can answer.

11 A. No, I don't remember any other specifics.

12 Q. And would there have been paperwork
13 associated with those meetings?

14 MR. TSAI: Object to scope.

15 Q. (By Ms. Herzfeld) A report or e-mail or
16 something you'd write on the way back?

17 A. Something was probably generated, not
18 necessarily by myself, but by others who were there.

19 Q. And if I were looking for those, where
20 would I look?

21 MR. TSAI: Object to scope.

22 A. E-mails.

23 Q. (By Ms. Herzfeld) E-mails? Okay. And
24 you probably would have been copied on them, would be

1 my guess?

2 MR. TSAI: Object to scope.

3 A. That's possible.

4 Q. (By Ms. Herzfeld) So they weren't sales
5 calls, you didn't talk about diversion, you didn't talk
6 about abuse of opioids. Did you talk about
7 chargebacks?

8 MR. TSAI: Object to scope. Not a proper
9 30(b)6 question. Go ahead.

10 A. No, from my recollection we talked with
11 McKesson about their general operation, about any --
12 like any feedback that we had for them about the
13 ordering process, any feedback they had for us about
14 how product was packaged or shipped. The visit with
15 AcelRx was relative to seeing their operation, talking
16 to them in general about their business and goals for
17 the future. No specific decisions were made that I can
18 recall.

19 Q. (By Ms. Herzfeld) And as we talked
20 before, you said generally there were some differences
21 based on individual salespeople -- I'm paraphrasing
22 you, so tell me if I'm wrong here -- on their
23 compensation, but the general compensation scheme was
24 somewhat uniform; is that right?

1 A. So --

2 MR. TSAI: Object to form. Go ahead.

3 A. So the compensation program was developed
4 in a consistent manner. The incentive compensation
5 plan was set up consistently across territories. The
6 individual territory targets were set on a
7 territory-by-territory basis, and so the goals that
8 sales representatives were measured against were
9 territory-specific. The way they were compensated on
10 those goals was consistent.

11 Q. (By Ms. Herzfeld) And do you know
12 anything about the Nashville district and their goals
13 being different? Do you know any of the specifics on
14 that?

15 A. I do not.

16 Q. And then earlier you talked about 852s or
17 867 sales plans. Do you remember those conversations?

18 A. We discussed 852 and 867 data.

19 Q. Data. Okay. Did you have any companies
20 that had 852 or 867 arrangements with Mallinckrodt in
21 Tennessee?

22 A. I am not aware if we had any customers in
23 Tennessee who had those arrangements.

24 Q. And where could I look to find that

1 information?

2 A. The information about which customers
3 provided us with those data feeds would be contained
4 within the distribution agreements with those
5 customers.

6 Q. And how could I find out which
7 distribution agreements were in Tennessee with you all?
8 I'm assuming there's a bazillion of them. So are they
9 sorted in a way, are they in a database? How do they
10 know within like a state territory?

11 A. Well, so the distribution agreements
12 weren't set up on a state territory basis, and those
13 agreements were all national-level agreements, so you
14 would have to know who the entities are within
15 Tennessee that you were looking for and then find the
16 associated agreement.

17 Q. Could you look from -- could you do it
18 from the back end and search and see what information
19 was being provided from Tennessee and then undo it that
20 way?

21 A. I don't know if the EDI data streams
22 provide that kind of location information.

23 Q. Who would know that?

24 A. I'm trying to think of specific names.

1 Others within our company who handle those data streams
2 would be in the IT department. But I don't know who
3 those actual individuals are.

4 Q. Somebody in the IT department?

5 A. (Nodding "yes.")

6 Q. Yes?

7 A. Yes.

8 Q. Great. Was there any difference regarding
9 the chargeback programs or incentive or rebate programs
10 or other contractual agreements between the
11 jurisdictions that you discussed earlier and Tennessee,
12 or was everything kind of the same?

13 MR. TSAI: Object to form.

14 A. All of our chargeback agreements and
15 customer agreements were set up for the full
16 corporation, so the -- if the company was a national
17 company, the agreement applied consistently across the
18 country.

19 Q. (By Ms. Herzfeld) And what about if it
20 wasn't a national company? Say it was a regional
21 company or a smaller company. Was there kind of a
22 standard agreement for that, or how would that work?

23 A. All of these agreements were negotiated
24 agreements, most often were written on the distribution

1 customer's paper, and so they started the process and
2 were in the format that they chose. We negotiated
3 terms as part of establishment of the relationship, and
4 to the extent that these would be regional customers,
5 any of those regional distributor entities or regional
6 pharmacy chains, the agreement would apply consistently
7 throughout their entire region of business.

8 Q. And if I wanted to find out who
9 specifically was getting chargebacks in Tennessee, how
10 would I find that out?

11 A. Again, we would have to look at the
12 chargeback transactions and find any of those that were
13 Tennessee -- landed in Tennessee.

14 Q. And who would I ask for that? Would that
15 be IT or chargeback department? Who would that be?

16 A. That would be handled in our rebates
17 processing team.

18 Q. And then earlier you were talking about
19 the various types of information you had, the reports,
20 like the IMS data, the various other reports that you
21 could receive. Did you ever receive -- you meaning
22 Mallinckrodt -- ever receive data at a statewide level,
23 broken down by state?

24 A. In the past, we did receive IMS data which

1 were broken down at a state level for certain datasets,
2 prescription data specifically.

3 Q. When you say in the past, when was that?

4 A. So during the period of time that we
5 marketed branded opioid products, generally between
6 about 2008-2009 and 2015 or 2016, at that time we did
7 purchase what IMS refers to as subnational data, so
8 either in the Xponent data which gave physician-level
9 information, or in the subnational datasets. Both of
10 those datasets could be aggregated by state.

11 Q. And when you say it was broken down by
12 prescription datasets, what does that mean?

13 A. Generally IMS provides two different data
14 feeds which we purchase. One is sales information
15 relative to unit volumes, and that's unit volumes being
16 purchased by pharmacies, and then they also provide
17 prescription information which is a collection of
18 information and projection of total market relative to
19 prescriptions dispensed from pharmacies to patients.

20 Q. And who would have been responsible for
21 reviewing that state-level information?

22 A. That state-level information was reviewed
23 by the commercial analytics team or -- also called
24 global business insights and forecasting. That team

1 would have had access to state-level data, and as
2 necessary they would have looked at entire-state data.
3 More often they aggregated by territory and region.

4 Q. So I'm going to try to put this in a
5 little bit more understandable terms. So that IMS data
6 would show you from Tennessee -- I want to make sure
7 I'm understanding you, because I don't do the pharmacy
8 thing -- would show you, say, ox -- the generic
9 oxycodone -- how much of that was going to an
10 individual pharmacy?

11 A. IMS prescription data will show the number
12 of prescriptions filled for a given product, and state
13 was part of the identifier included.

14 Q. So it would show how many prescriptions
15 were filled for oxycodone for the State of Tennessee?

16 A. That would be one data point you could
17 analyze; correct.

18 Q. Could you also do it by county?

19 A. So in the Xponent dataset from IMS, we had
20 ZIP code-level information. I don't know if county was
21 represented or if you'd have to aggregate.

22 Q. But during those years -- I just want to
23 make sure I understand it. So during those years when
24 you all were getting that IMS data, 2008 to 2009 to

1 roughly 2015, you would get, for example, how much
2 oxycodone was being prescribed and/or filled by ZIP
3 code?

4 A. I'm not certain if we got that level of
5 data for prescribed. There's -- there are two
6 different views to the prescription data that IMS
7 provides. They do provide some view to prescribed
8 quantities, and then they do provide a view to
9 dispensed quantities. The gap in the middle is
10 anything that just doesn't get filled at the pharmacy.
11 And I know that the dispensed data we received at a
12 detailed ZIP code level. I don't know if we received
13 the prescriptions written data at that level.

14 Q. And who would know that?

15 A. That would probably at this point be a
16 matter of digging into the data and trying to find
17 what's in there.

18 Q. And so responsible for that, for looking
19 at that data and kind of ingesting it, would have been
20 the commercial analytics team; is that right?

21 A. That's correct. Yes.

22 Q. And do you know if the commercial
23 analytics team would communicate any of that
24 information to the sales team or to a suspicious order

1 monitoring team?

2 A. I know that commercial analytics
3 summarized results by territory and provided those
4 results to the sales team so that they could evaluate
5 performance.

6 Q. What about communicating those numbers to
7 the suspicious order monitoring folks?

8 MR. TSAI: Object to scope.

9 A. I am not aware if they did or not.

10 Q. (By Ms. Herzfeld) Who would know that?

11 A. The people involved in suspicious order
12 monitoring would know that.

13 Q. Do you know how long Mallinckrodt retains
14 that data?

15 MR. TSAI: Object to form.

16 A. How long we retain what?

17 Q. (By Ms. Herzfeld) The IMS data that you
18 received.

19 A. Many of the datasets, including the ZIP
20 code-level Xponent data, were -- our data feed was lost
21 when we ended the contract. We do have some archived
22 Xponent data. I don't know -- I can't personally speak
23 to how complete that data is for the entire period of
24 time we sold these products.

1 Q. And do you know who would know where that
2 information is?

3 A. So the data that we did have, the Xponent
4 data that we did have has been produced.

5 Q. In the MDL?

6 A. I believe so.

7 Q. To your lawyers? Yes?

8 A. Yes.

9 Q. And how do you know it's been produced?

10 A. I was told that it has been.

11 Q. Were you involved in producing it
12 personally?

13 A. Not personally involved, no.

14 Q. Were people that report to you involved in
15 producing it?

16 A. I helped identify that it may still exist
17 and told people where to look.

18 Q. Great. Okay. Fantastic. And then
19 earlier on you were talking about -- strike -- hold on
20 for just one second. Okay. Earlier on you were
21 talking about different databases and reports that
22 Mallinckrodt consults in connection with the sale,
23 marketing, or distribution of its opioid products, and
24 when you talked about all of those, were there any

1 specific reports other than the IMS data that we just
2 talked about that would have had to do with Tennessee?

3 A. Outside of IMS data, I'm not aware of any
4 Tennessee-specific reports.

5 Q. What about any reports that were created
6 or that you ever saw that would have to do with maybe
7 the Appalachian region of Tennessee or the Appalachian
8 region of the country?

9 A. I'm not aware of any specific reports of
10 that nature.

11 Q. What about regional reports? Maybe the
12 U.S. south? Did you ever see any regional reports
13 about opioid use or sales and marketing of opioids in
14 the south of the United States?

15 A. No.

16 Q. And when you were talking about your
17 marketing expenditures earlier, are those broken down
18 by region at all?

19 A. No, our marketing expenditures for branded
20 products were at most broken down by the product, but
21 not detailed at a regional level.

22 Q. Which reminds me. I had a question from
23 earlier that I meant to follow up on. When you talk
24 about branded opioid products, you talked about -- and

1 I'm going to totally mispronounce this. It was the
2 "Xart-emis"?

3 A. "Xar-temis."

4 Q. "Xar-temis"? Okay.

5 A. Or "Xar-tem-is."

6 Q. "Xar-tem-is." You say it differently than
7 I do, and I'm sure you're correct and I've just read it
8 too much. Okay. And then Exalgo?

9 A. Correct.

10 Q. Am I saying that one right?

11 A. Yes.

12 Q. And then you talked a little bit about
13 Roxicodone being a branded opioid. Is that right?

14 A. Roxicodone itself is technically a branded
15 product. It is classified as a brand by FDA, has that
16 brand name on the label. Mallinckrodt owns the asset,
17 owns the rights to that product, and we do still
18 manufacture and sell that product in very small
19 quantities. We have never promoted or marketed that
20 product.

21 Q. And then there's also a generic of that
22 Roxicodone?

23 MR. TSAI: Objection. Asked and answered.
24 Duplicative. Go ahead.

1 A. Mallinckrodt and about 12 other companies
2 make a generic Roxicodone.

3 Q. (By Ms. Herzfeld) So now we've talked
4 about Xartemis -- probably still missed it up --
5 Exalgo, Roxicodone. Were there other branded products
6 that Mallinckrodt had?

7 MR. TSAI: Objection. Asked and answered.
8 Duplicative.

9 A. At one point in time we did also sell
10 Magnacet.

11 Q. (By Ms. Herzfeld) Okay. Yeah.

12 A. And we did sell a product that contained
13 an opioid but was not a pain product, and that's
14 TussiCaps.

15 Q. We talked about those before. Other than
16 that, anything else? Those were kind of the --

17 A. Those are the only ones.

18 Q. Great. Okay. And do you know if the
19 marketing results for your branded products are broken
20 down by region at all?

21 MR. TSAI: Objection to the term marketing
22 results. Go ahead.

23 A. Our sales results would have been broken
24 down by sales territory and by region, and that would

1 have been in terms of prescriptions of our products.

2 Q. (By Ms. Herzfeld) So when you were
3 talking before about kind of tracking your return on
4 investment, I want to make sure I understood that as
5 well. So I want to -- I'm going to back it way up.
6 We're going to go real basic. So Mallinckrodt
7 generally is going to spend some money on marketing its
8 products and trying to target people in order to get
9 them to prescribe their products; right?

10 MR. TSAI: Objection to the form.

11 A. We generally had a marketing budget for
12 our branded products in order to support our selling
13 efforts.

14 Q. (By Ms. Herzfeld) And then you can tell
15 if those marketing efforts have been successful or not
16 by how many prescriptions are written for your product
17 in a particular territory; is that right?

18 MR. TSAI: Object to the form.

19 A. In terms of analyzing specific marketing
20 efforts, it's really difficult to determine when an
21 individual marketing effort has been successful. In
22 general, when we set our plans and our marketing
23 budgets, we looked at our overall expectations for the
24 amount of activity that our sales team was going to

1 make in a given year and the expectations around market
2 share or growth in market share for our products. When
3 doing that, we determined what a reasonable marketing
4 budget would be based on the efforts that we thought
5 were needed and what those efforts cost.

6 Q. (By Ms. Herzfeld) And is any of that
7 broken down by region or state?

8 A. No.

9 Q. So everything is just kind of nationally
10 this is what we're doing? You're not doing a different
11 marketing plan for a region, for example?

12 A. No, all of our efforts were national
13 level.

14 Q. You said before that you're aware of the
15 opioid crisis. Are you aware specifically about the
16 opioid crisis in Tennessee?

17 A. I am not aware of specific details about
18 the situation in Tennessee.

19 Q. Have you ever heard of something called
20 neonatal abstinence syndrome?

21 MR. TSAI: Objection to scope.

22 A. I believe I have seen the term.

23 Q. (By Ms. Herzfeld) And what do you
24 understand it to be?

1 A. I believe it is a situation involving
2 neonates born to mothers who had been taking opioids
3 prior to delivery and those neonates then being free of
4 the opioid.

5 Q. Being free of the opioid?

6 A. Not receiving the opioid anymore, or
7 however you want to say it.

8 Q. You're saying it in a various scientific
9 way. If you say it in another way, is it babies that
10 are born dependent on opioids to your understanding?

11 A. To my understanding that's the resulting
12 condition, when a baby is born dependent upon opioids.

13 Q. And do you know where Tennessee ranks in
14 the number of babies that are born with neonatal
15 abstinence syndrome?

16 A. No, I don't.

17 Q. When is the first time you think you've
18 heard about neonatal abstinence syndrome?

19 A. The first time I heard the term I believe
20 was when reading the label for Exalgo.

21 Q. Have you ever been involved in any
22 meetings or any discussions about neonatal abstinence
23 syndrome in any of Mallinckrodt's products?

24 A. No, I have not.

1 Q. What about for opioids in general?

2 A. No, I have not.

3 Q. Have you ever heard of the acronym HIDTA?

4 H -- I'm sorry. A-H-I-D-T-A.

5 A. No, I don't think so.

6 Q. Have you ever heard of something called
7 the Appalachian High-Intensity Drug Trafficking Area?

8 MR. TSAI: Objection to scope.

9 A. Yeah, I don't think so.

10 Q. (By Ms. Herzfeld) Do you know if anyone
11 at Mallinckrodt was looking at rates of NAS in east
12 Tennessee?

13 A. I am not aware if anyone was looking at
14 that.

15 Q. And who -- if I were to try to figure out
16 who would have been, do you know which department that
17 would have fallen under?

18 A. So market surveillance of adverse events
19 would have been the responsibility of
20 pharmacovigilance.

21 Q. And would that same department have also
22 been monitoring opioid-related deaths?

23 A. That same department would have monitored
24 reports of deaths or other adverse events related to

1 specifically our products.

2 Q. When you say specifically our products,
3 what do you mean?

4 A. Relating specifically to reports involving
5 specific Mallinckrodt products as opposed to general
6 opioid reports.

7 Q. So if it was oxycodone, if they didn't
8 know it was Mallinckrodt, you wouldn't necessarily have
9 been monitoring that, but if it's Mallinckrodt opioid,
10 then that's something that would have been monitored?

11 A. It's my general understanding that the
12 pharmacovigilance processes didn't capture information
13 on unidentified products of that nature.

14 Q. Do you know how products were identified
15 if somebody dies -- which product?

16 A. I don't know the details of how that would
17 be identified. I'm sure it would be different
18 depending on the case.

19 Q. Earlier you were talking about the process
20 used to determine which medical professionals your
21 sales representatives would individually contact with
22 respect to your opioid products. Do you remember that
23 conversation from earlier today?

24 A. Yes.

1 Q. Do you know who the sales reps targeted in
2 Tennessee?

3 A. I don't know specifically who they
4 targeted, no.

5 Q. Do you know who would?

6 A. I don't believe there's anyone at the
7 company who would know those specifics, and I don't
8 know if there are still documents that would have that.

9 Q. Why would there not be documents about
10 that anymore?

11 A. I'm just not aware of those documents.

12 Q. And why would nobody from the company know
13 anymore?

14 A. There are very few people still with our
15 company who sold these products in the past, and those
16 who are with the company were not directly involved
17 with that level of detail.

18 Q. And when did you -- I'm sorry. I think
19 you had said that before. Was it 2015 that that
20 program stopped?

21 A. Generally 2015 our marketing efforts
22 around branded opioids ceased.

23 Q. And that would be your specific sales --
24 targeting of doctors for sales as well?

1 A. Targeting doctors for sales, creation of
2 marketing materials and marketing plans.

3 Q. So you don't know if anyone was flagged
4 for removal from a sales target list for Mallinckrodt
5 in Tennessee?

6 A. I don't know specific to Tennessee, no.

7 Q. Do you know where I could find that
8 information, or is your answer the same?

9 A. You would have to find the old sales
10 plans, and I don't know where those are kept.

11 Q. Somebody in the sales department would
12 know?

13 A. Well, sales department doesn't exist
14 anymore, so it would probably be captured in e-mails
15 and other collected correspondence.

16 Q. To your knowledge there weren't any
17 documents that were destroyed by Mallinckrodt about
18 sales?

19 A. Not to my knowledge, no.

20 Q. So you didn't see anything there was like,
21 okay, the sales department's going away, let's get rid
22 of all the documents?

23 A. I didn't hear of anything like that, no.

24 Q. So hypothetically the documents should

1 still exist, just probably in a different spot?

2 MR. TSAI: Object to form.

3 A. Hypothetically.

4 Q. (By Ms. Herzfeld) Did Mallinckrodt
5 distribute opioids to online retailers?

6 MR. TSAI: Object to scope. There's a
7 specific topic about online pharmacies that's
8 designated for a different witness.

9 MS. HERZFELD: Okay, but I think it's also
10 encompassed in Number 27.

11 Q. (By Ms. Herzfeld) So did Mallinckrodt
12 distribute opioids to online retailers?

13 MR. TSAI: Object to scope. 27 reads to
14 the extent not encompassed with other topics, and
15 there's a specific topic about online.

16 Q. (By Ms. Herzfeld) Okay. You can answer
17 the question?

18 MR. TSAI: Same objection.

19 A. I am not aware of ever selling opioids to
20 online retailers.

21 Q. (By Ms. Herzfeld) Have you ever heard of
22 a person named Abdelrahman Mohamed?

23 A. No, I don't think so.

24 Q. A prescriber in Tennessee?

1 A. Huh-uh. No.

2 Q. What about Timothy Gouter (ph)?

3 A. No, I don't think so.

4 Q. So you haven't been involved in any
5 discussions about Mr. Mohamed or Mr. Gouter?

6 A. No.

7 Q. What about Gary Arlenmore (ph)?

8 A. No, I don't believe so.

9 Q. Have you ever heard of a doctor named
10 David Florence?

11 A. No.

12 Q. He also had a very brief reality show
13 called DocStar. Have you heard of DocStar?

14 MR. TSAI: Objection to scope.

15 A. No, I've never heard of that.

16 Q. (By Ms. Herzfeld) What about Mark Murphy?

17 A. No.

18 Q. Ed White?

19 A. I know a person named Ed White. I don't
20 know if it's the same person.

21 Q. Does the Ed White that you know live in
22 Tennessee?

23 A. I don't believe so.

24 Q. Does he operate a medical clinic of some

1 sort?

2 A. No, he does not.

3 Q. Different guy. Okay. What about Pam
4 White?

5 MR. TSAI: Objection to scope.

6 A. No.

7 Q. (By Ms. Herzfeld) Did you ever hear any
8 discussions about any particular medical clinics or
9 doctors' offices within Tennessee during your time at
10 Mallinckrodt?

11 A. No, not that I can recall.

12 Q. Were you involved at all in the DEA
13 investigation of Sunrise Wholesale in Delray Beach,
14 Florida?

15 MR. TSAI: Objection to scope. DEA
16 matters are specifically designated in other topics
17 designated for another witness.

18 MS. HERZFELD: Okay.

19 A. No, I was not involved.

20 Q. (By Ms. Herzfeld) Do you know what
21 Mallinckrodt's share was of the opioid market in
22 Tennessee?

23 A. No, I do not.

24 Q. And I'm going to give you some different

1 times. From 2005 to 2010 did you know what the market
2 share was of Mallinckrodt opioids in Tennessee?

3 A. No, we never analyzed share of opioid
4 market in -- by state at all.

5 Q. And what about from 2010 to the present?

6 A. No, I do not know.

7 Q. Have you ever heard of Tennessee being
8 referred to as ground zero for the opioid crisis?

9 A. No, I don't think so.

10 Q. What about West Virginia?

11 MR. TSAI: Objection to scope.

12 A. I don't know if I've heard the specific
13 term ground zero, but I have heard about West Virginia.

14 Q. (By Ms. Herzfeld) Have you heard
15 generally about Appalachia, kind of West Virginia,
16 Kentucky, the mountain region, being particularly hard
17 hit by opioid abuse issues?

18 A. I'm personally away from the news media
19 about the opioid issues in the Appalachia region.

20 Q. And when do you think you first became
21 aware of that?

22 A. I don't remember specifically. If I had
23 to guess it would be somewhere around maybe 2010.

24 Q. Do you know how you became aware of it?

1 A. The press and the news media.

2 Q. Not through your official duties at
3 Mallinckrodt?

4 A. No.

5 Q. Have you ever heard of something called
6 the Oxy Express?

7 MR. TSAI: Objection to scope.

8 A. No.

9 Q. (By Ms. Herzfeld) Have you heard about
10 I-75 being a drug trafficking corridor from Florida to
11 Ohio?

12 MR. TSAI: Objection to scope. This is
13 getting into diversion issues that are designated for a
14 different witness.

15 MS. HERZFELD: Also has to do with abuse.

16 A. I don't know if I've heard specifically
17 about I-75, no.

18 Q. (By Ms. Herzfeld) Have you heard
19 generally about there being some highway, some --
20 taking pills from Florida up north?

21 A. I've heard generally about a pattern of
22 involvement with Florida.

23 Q. And where did you hear that?

24 A. Again, generally in the news media.

1 Q. But not through your official involvement
2 at Mallinckrodt?

3 A. Not that I can recall.

4 Q. So based on this information that you had
5 from Appalachia being particularly hard hit by the
6 opioid abuse epidemic and this kind of movement of
7 pills going from Florida up north, was there any
8 differential or different way that the Appalachian
9 states were treated at all by Mallinckrodt in any of
10 the topics we've discussed today?

11 MR. TSAI: Objection to the form of the
12 question.

13 A. So when we -- in the generics business,
14 when we contract with our wholesale and distributor
15 customers or with pharmacy chains, we contract with
16 them based upon their entire scope of operation,
17 whether that's nationwide or regional, and we have
18 processes in place that allow us to work with them to
19 ensure that both sides are complying with the
20 regulations involved with shipment of the products that
21 we sell them. If there are specific issues with an
22 individual distribution center or pharmacy chain or
23 other type of customer, we have processes in place to
24 address that.

1 Q. (By Ms. Herzfeld) So that's a very long
2 answer about very specific things, but my question is,
3 was there any sort of a regional change that was made,
4 like, hey, guys, we got this issue going on in
5 Appalachia, so we're going to watch our customers'
6 customers to see what's going on, who they're shipping
7 to, or we're going to put out an alert to all of our
8 customers that they need to watch their customers'
9 customers to see what's going on in the Appalachian
10 region? Was there any differential in that regard?

11 MR. TSAI: Objection to the form of the
12 question. Beyond the scope of the topics for this
13 witness.

14 A. I am not aware of anything like that that
15 occurred and am not prepared to speak to that.

16 Q. (By Ms. Herzfeld) So -- but the topics
17 you did speak on today, though, having to do with
18 abuse, having to do with sales, having to do with
19 compensation, having to do with chargeback
20 information -- all the topics that you've talked about,
21 I just want to be clear that there wasn't any
22 differential that was for the Appalachian region or for
23 Tennessee.

24 MR. TSAI: Objection to the form of the

1 question.

2 A. Any of the programs that you mentioned
3 relative to targeting and incentivizing the branded
4 sales team or administering contracts with our
5 distribution partners were all established at a
6 national level consistent with our overall plans or
7 business processes.

8 Q. (By Ms. Herzfeld) So to piggyback off of
9 that, and so nothing was -- nobody was treated
10 differently if they were in Appalachia or Tennessee?
11 You treated all states the same?

12 MR. TSAI: Objection to the form.

13 A. Our decisions were made for individual
14 distributors or prescribers based upon the activity at
15 that particular customer or prescriber, and it was not
16 catered to a certain region but more to the specific
17 activity.

18 Q. (By Ms. Herzfeld) So I'm going to repeat
19 my question one more time so I can be really clear
20 about it. I just want to know, for sales or for
21 compensation or incentives or any of those things that
22 you've talked about -- I understand you're saying
23 sometimes things are treated differently based on
24 individual circumstances, but from a regional or a

1 state level, everything was the same, nobody was
2 treated differently in Appalachia or Tennessee as they
3 were countrywide?

4 MR. TSAI: Objection to form.

5 Q. (By Ms. Herzfeld) It's just a yes or no.

6 MR. TSAI: Objection to form.

7 A. I still will go back to my same answer
8 that the plans we put in place were consistent on a
9 nationwide basis and consistent across our business.
10 If there were individual health care practitioners or
11 individual distributors or wholesalers purchasing
12 product from us that did not abide by the agreements
13 that were in place, we took action on that specific
14 incident. We did not take action on a regional basis
15 based upon other information.

16 Q. (By Ms. Herzfeld) Or on a statewide basis
17 based on other information?

18 THE WITNESS: Or on a statewide basis.
19 That's correct.

20 MS. HERZFELD: If we can just go off the
21 record for a minute, please.

22 THE VIDEOGRAPHER: We are going off the
23 record at 5:31 PM.

24 [Whereupon the proceedings were

1 concluded.]

2 [5:31 p.m.]

3 [SIGNATURE RESERVED.]

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C E R T I F I C A T E

I, JOHN ARNDT, a Certified Shorthand Reporter and Certified Court Reporter, do hereby certify that prior to the commencement of the examination, KEVIN VORDERSTRASSE was sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the proceedings as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

JOHN ARNDT, CSR, CCR, RDR, CRR
CSR No. 084-004605
CCR No. 1186

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I, KEVIN VORDERSTRASSE, the witness

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herein, having read the foregoing testimony of the

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pages of this deposition, do hereby certify it to be a

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true and correct transcript, subject to the

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corrections, if any, shown on the attached page.

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KEVIN VORDERSTRASSE

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Sworn and subscribed to before me,

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This _____ day of _____, 201_.

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Notary Public

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KEVIN VORDERSTRASSE